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(54) **INSTRUMENT DEVICE MANIPULATOR WITH TENSION SENSING APPARATUS**

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(58) **Field of Classification Search**

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See application file for complete search history.

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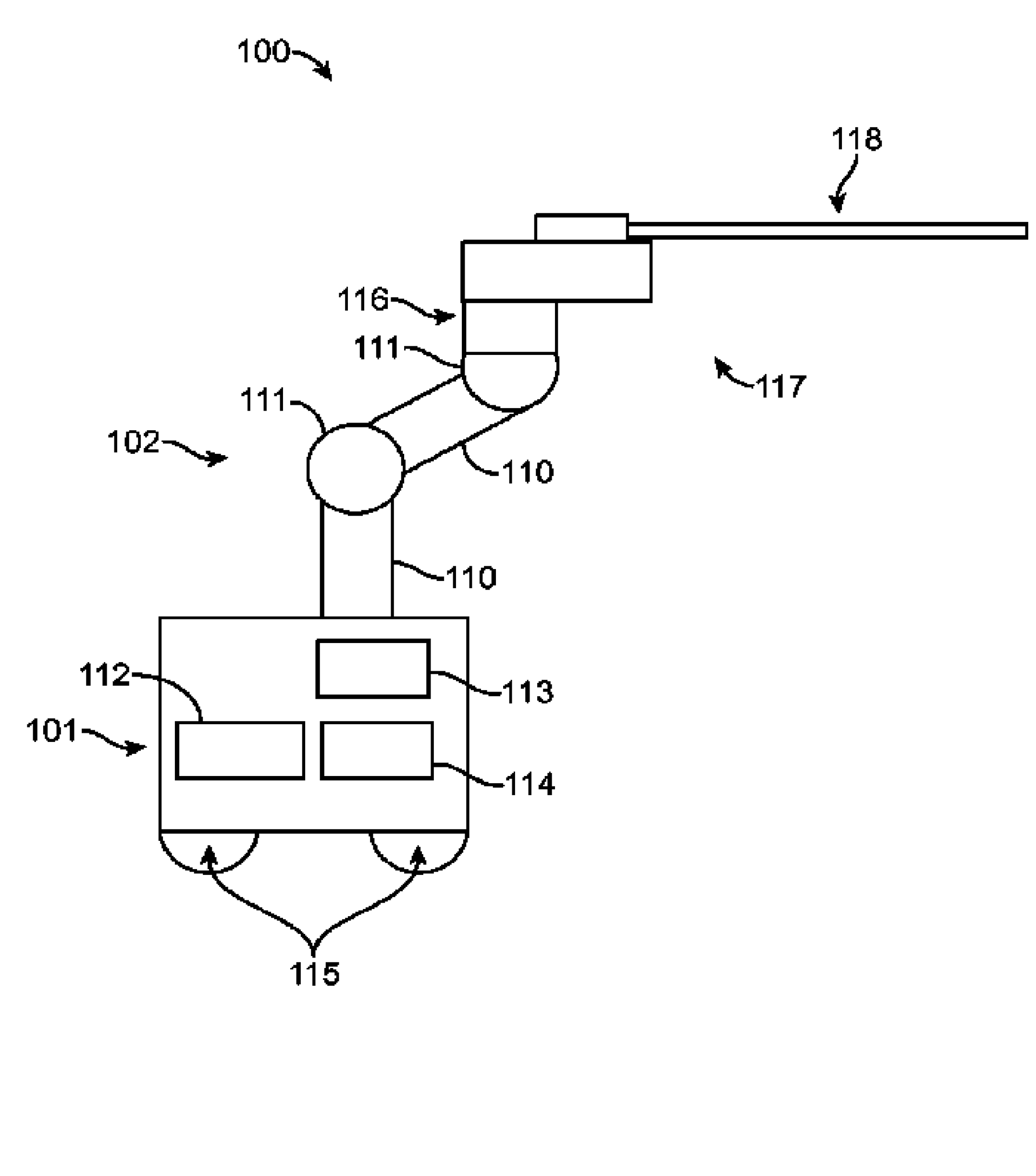
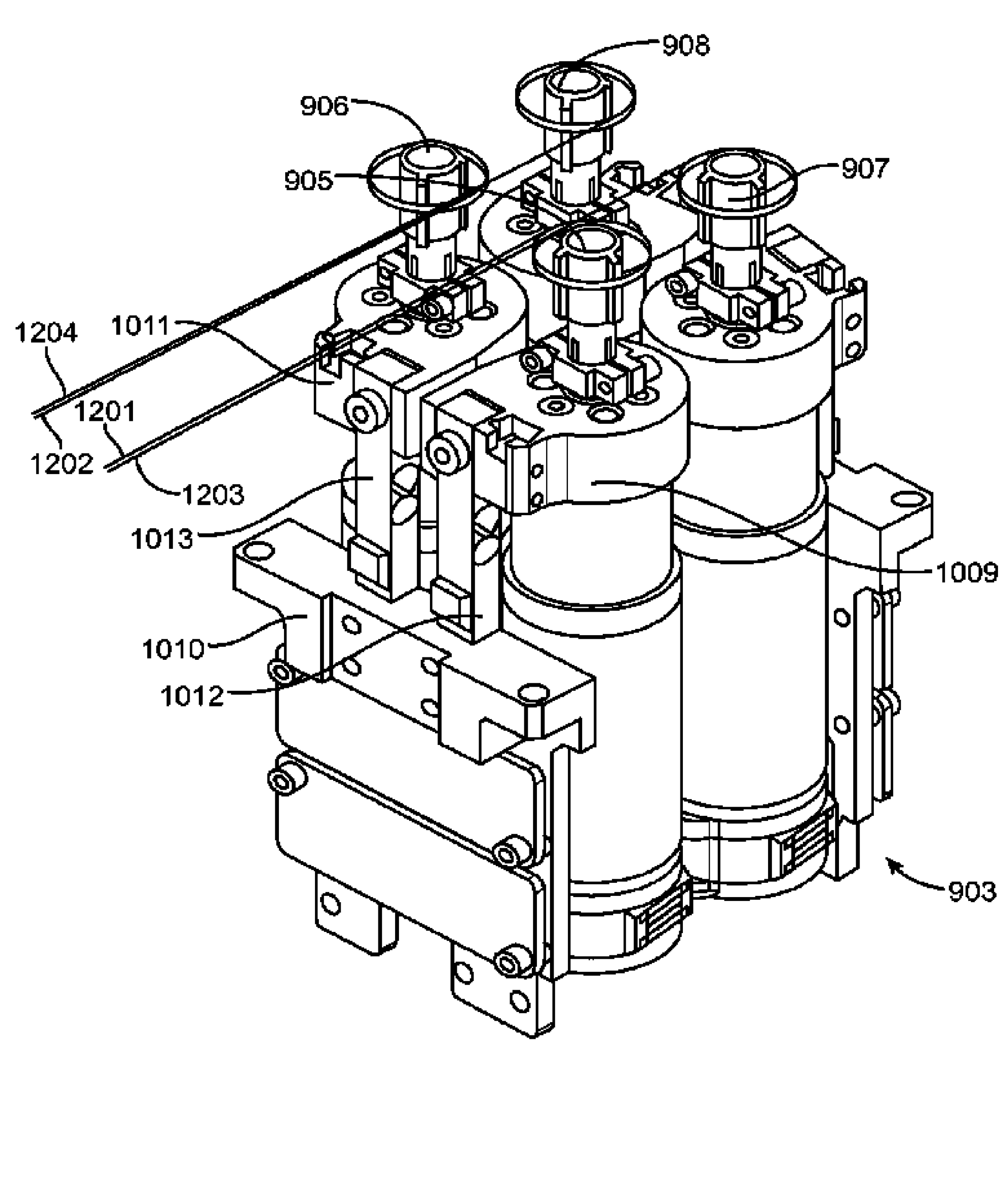
(57) **ABSTRACT**

An endolumenal robotic system provides the surgeon with the ability to drive a robotically-driven endoscopic device to a desired anatomical position in a patient without the need for awkward motions and positions, while also enjoying improved image quality from a digital camera mounted on the endoscopic device.

22 Claims, 59 Drawing Sheets





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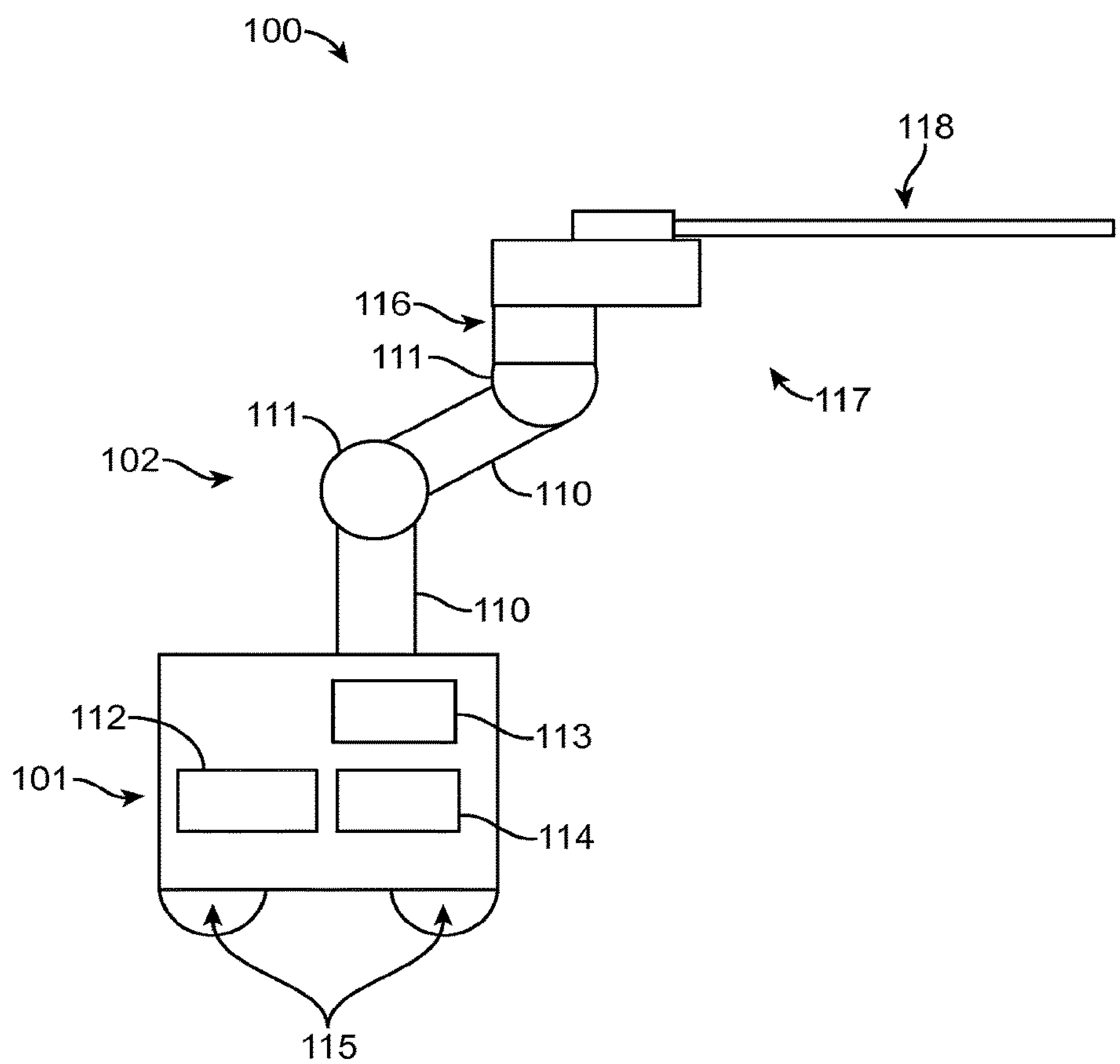


FIG. 1

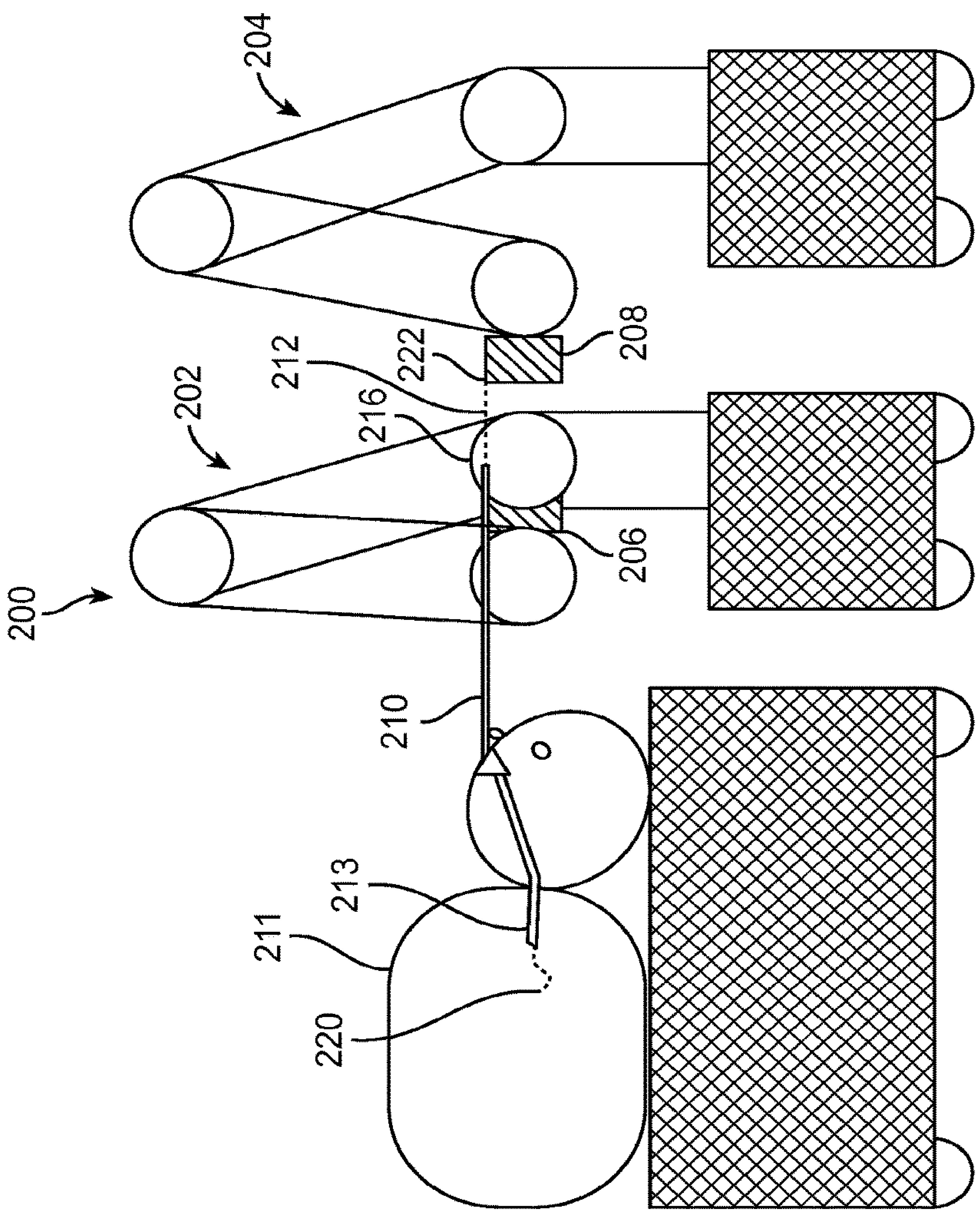


FIG. 2A

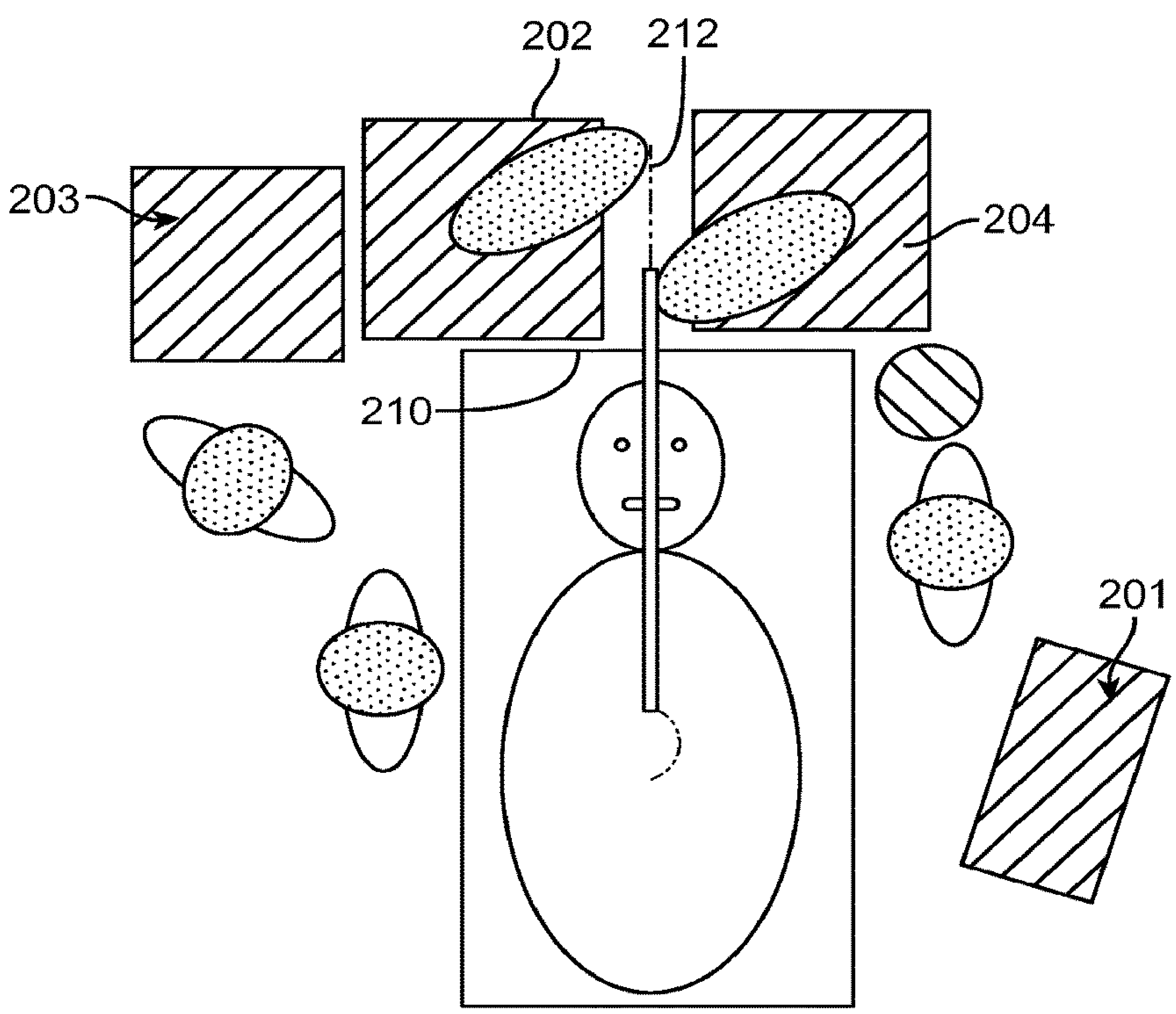


FIG. 2B

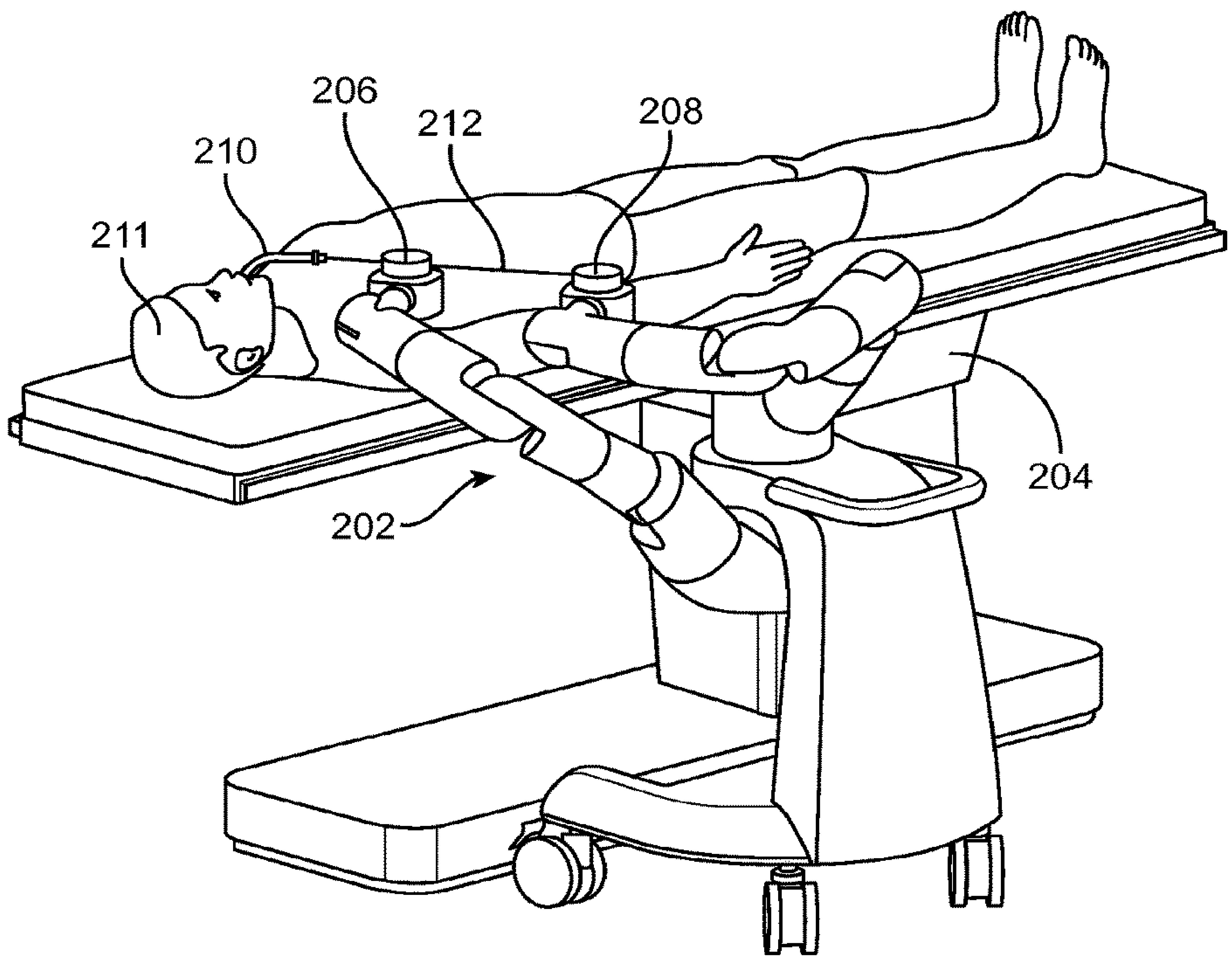


FIG. 2C

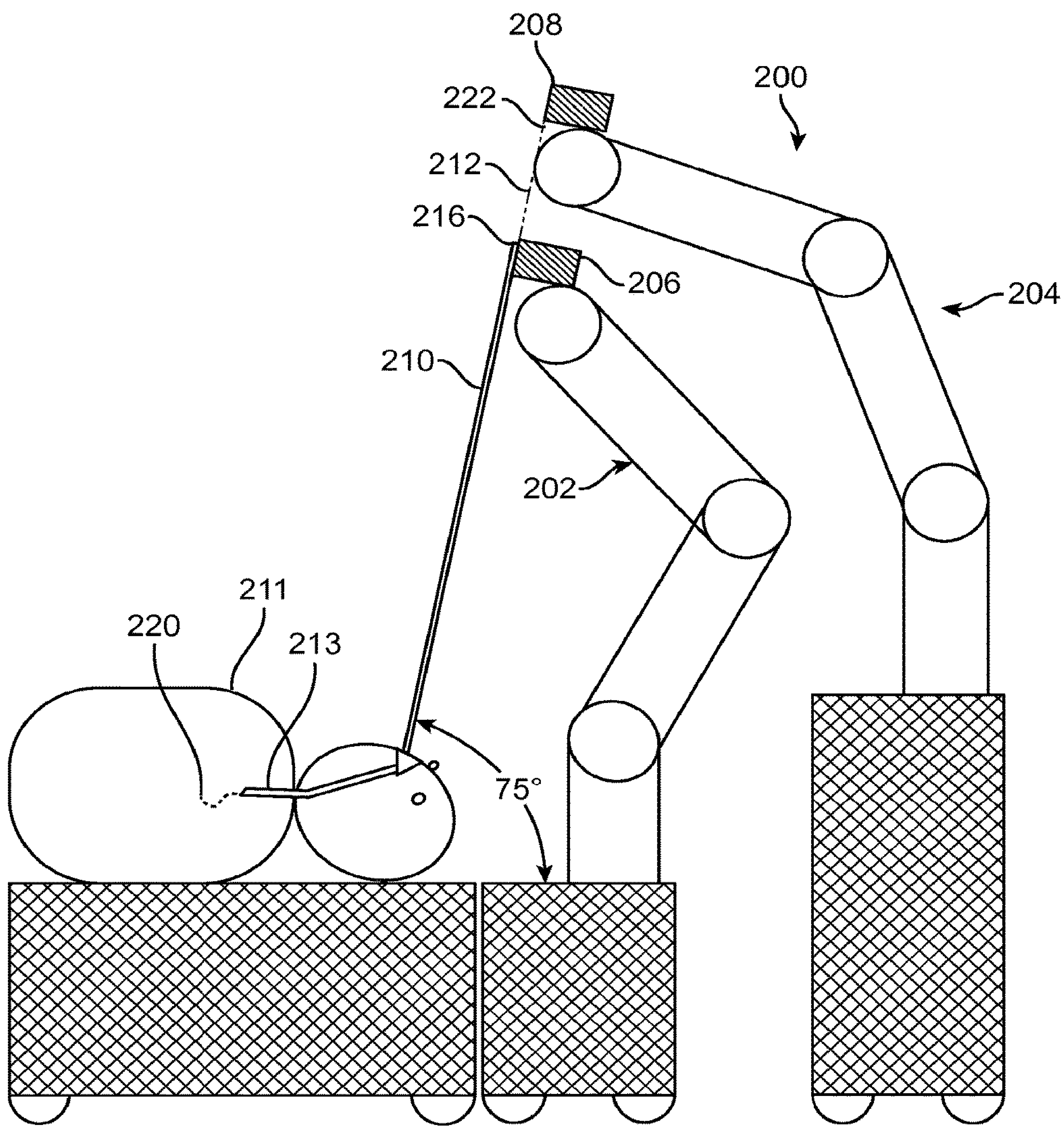


FIG. 2D

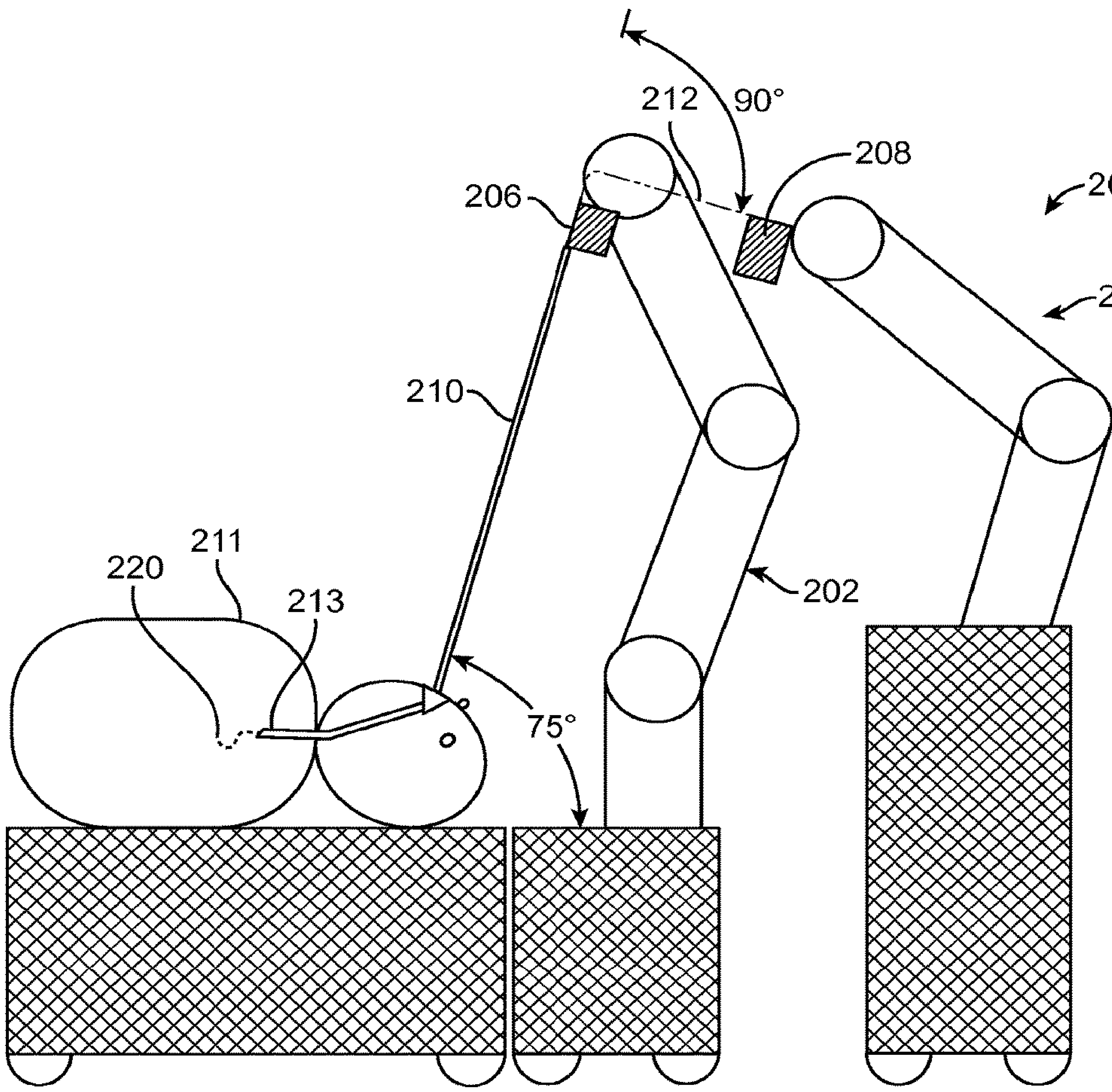


FIG. 2E

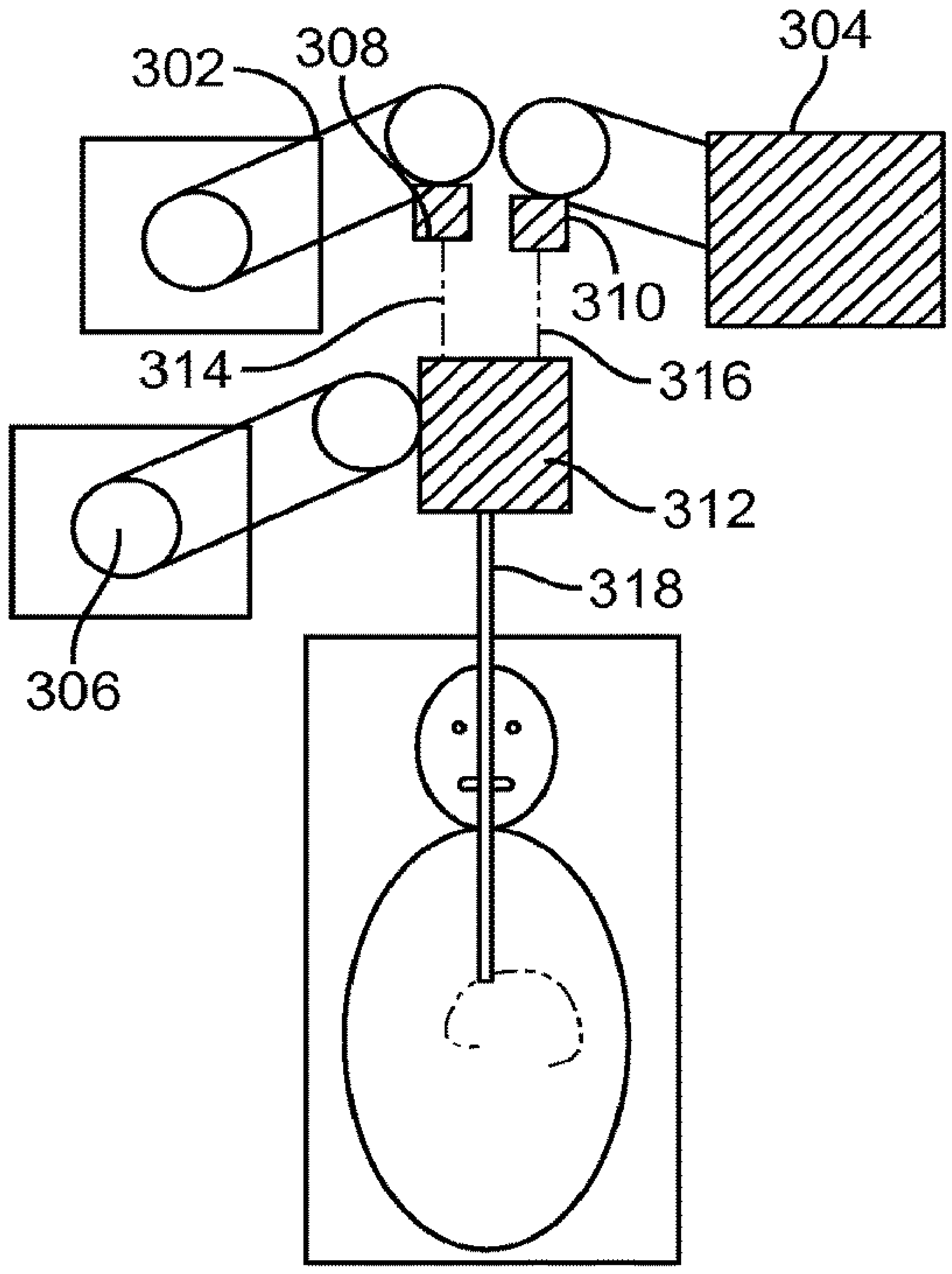


FIG. 3A

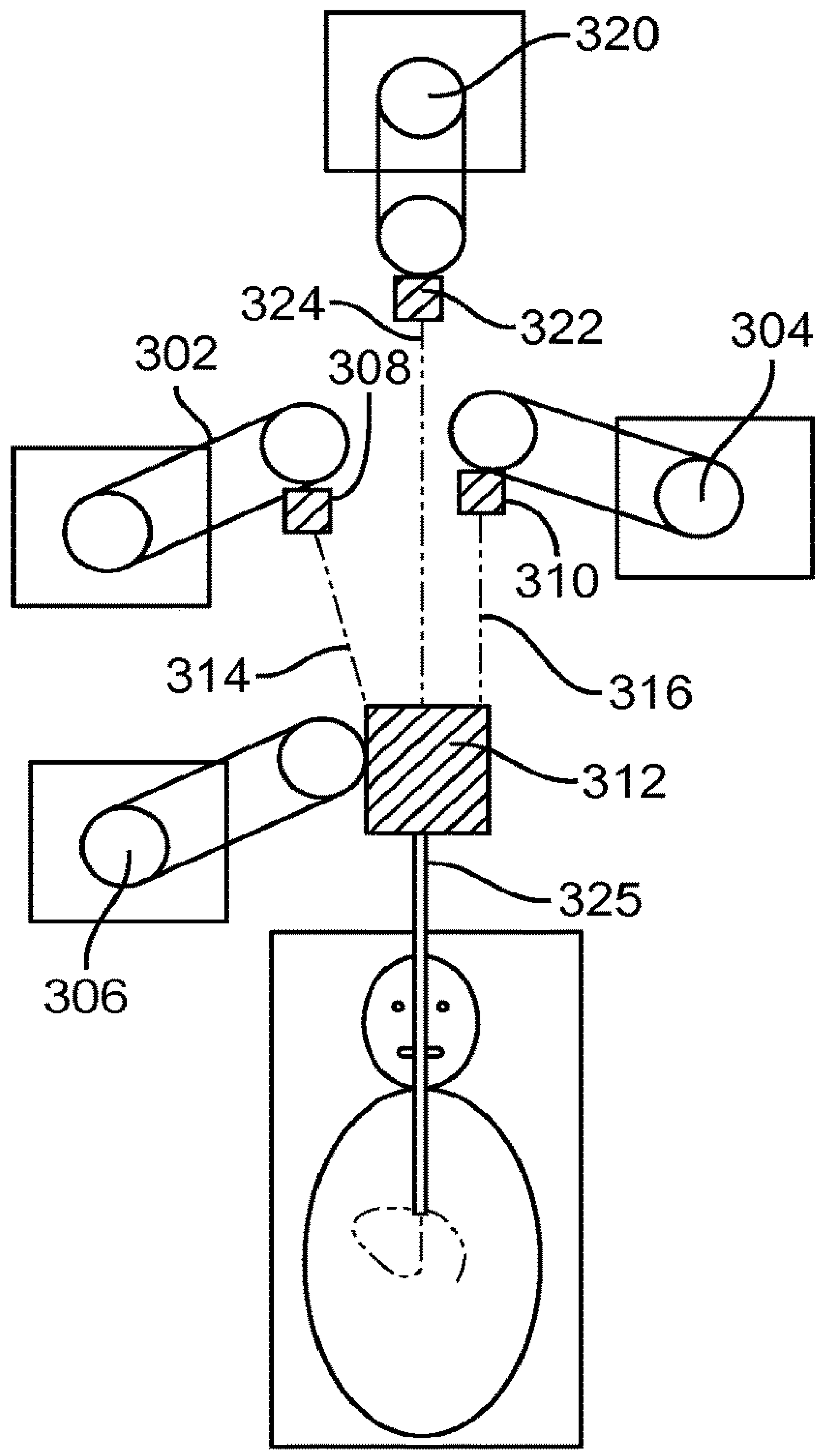


FIG. 3B

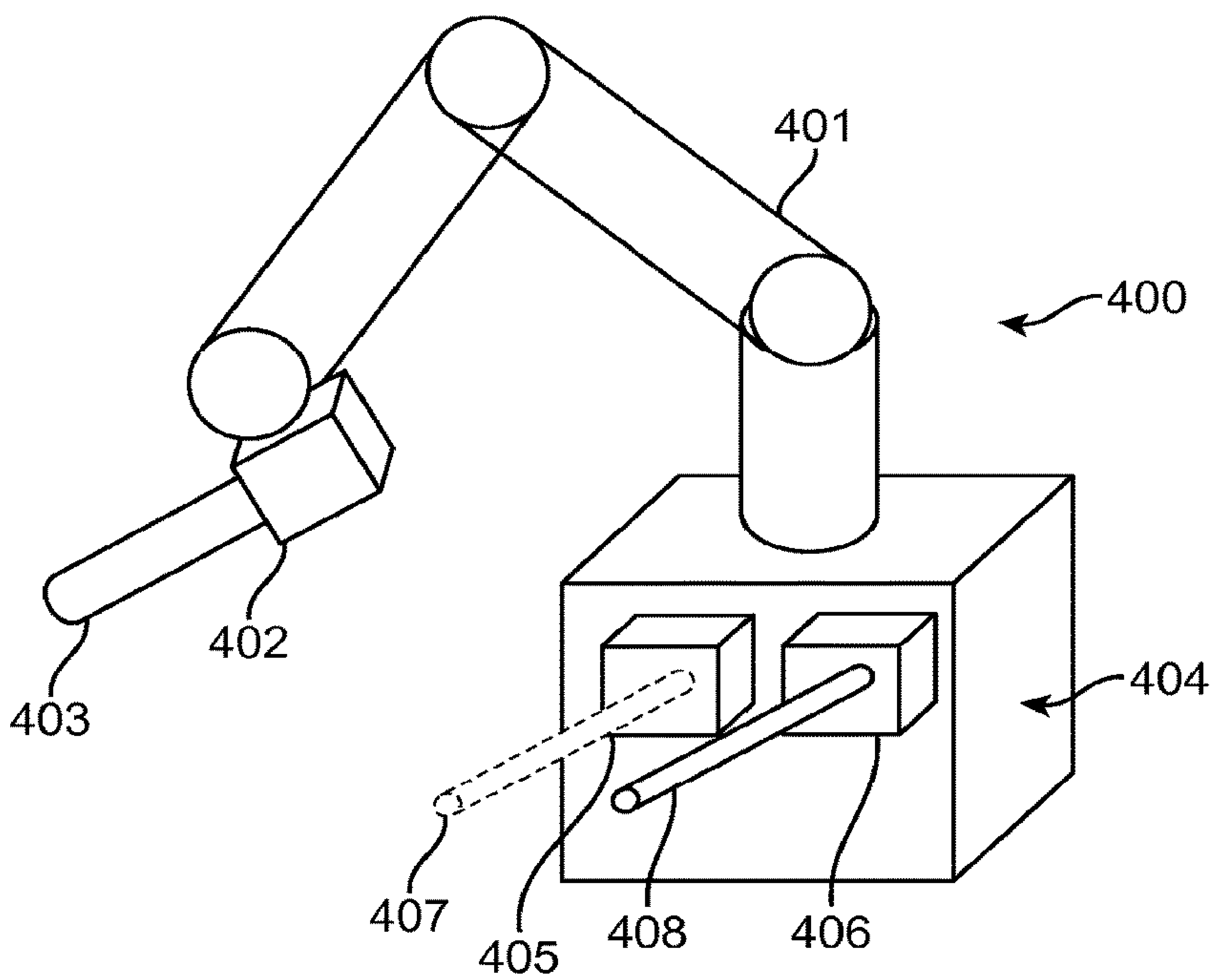


FIG. 4

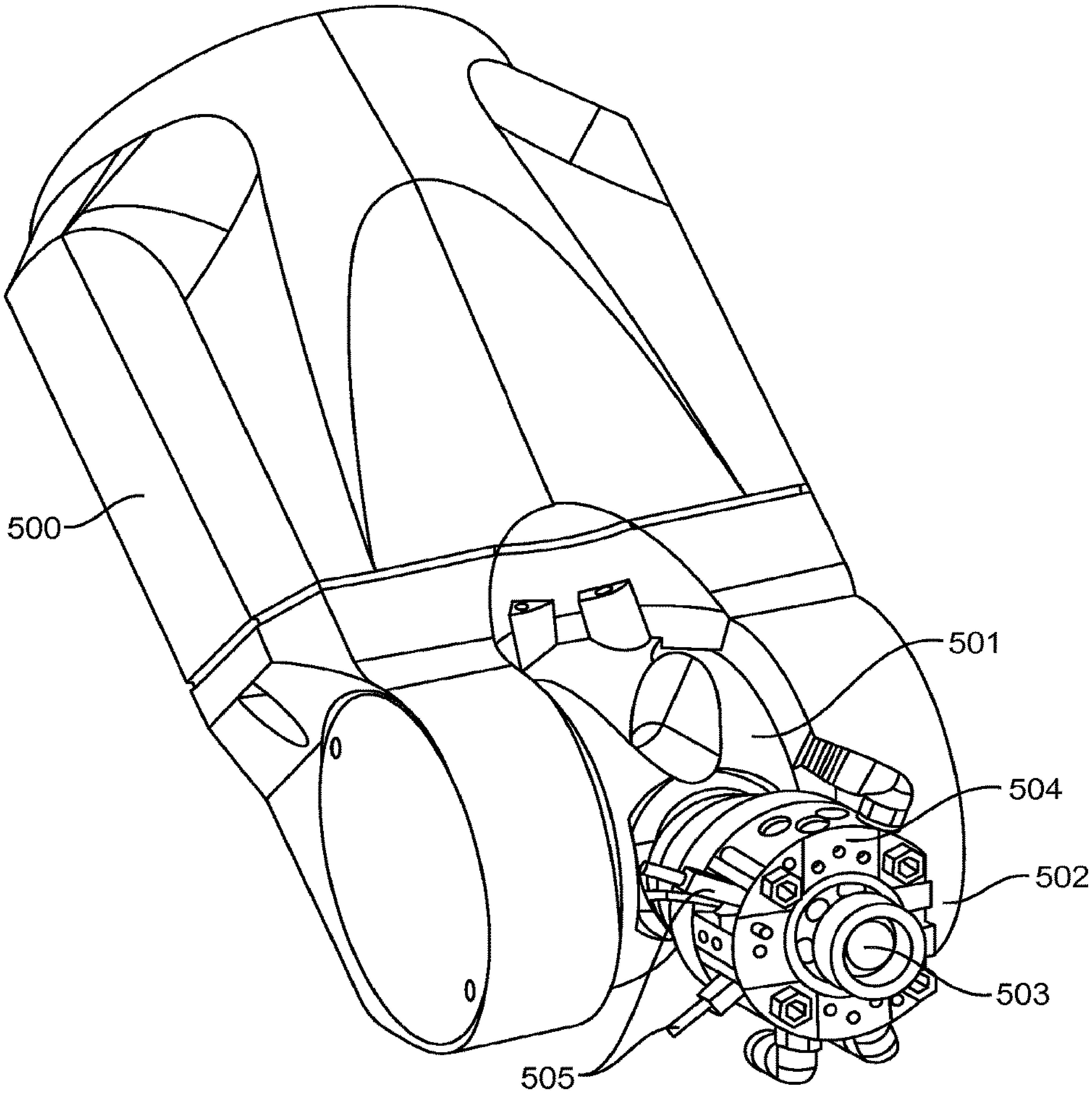


FIG. 5A

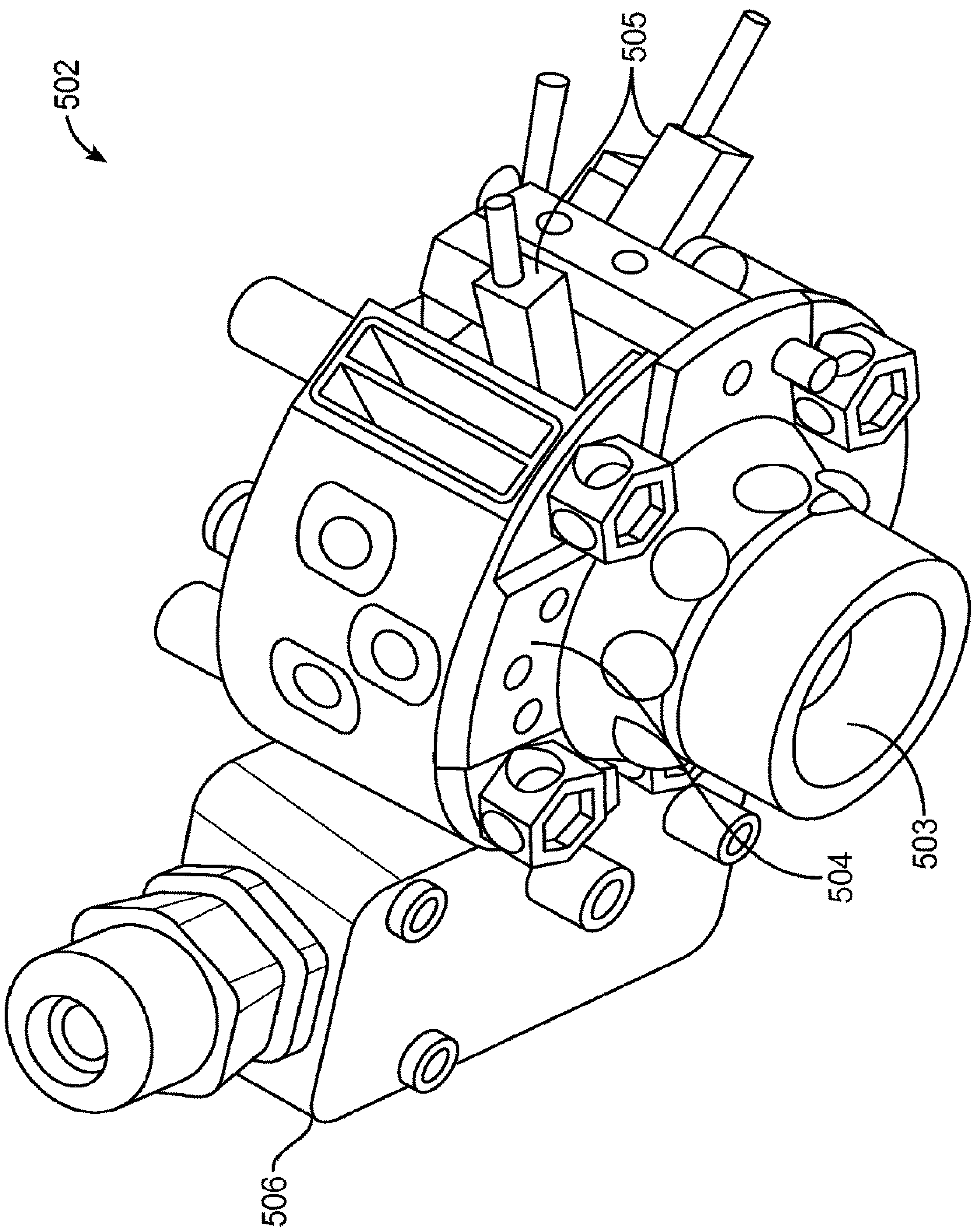


FIG. 5B

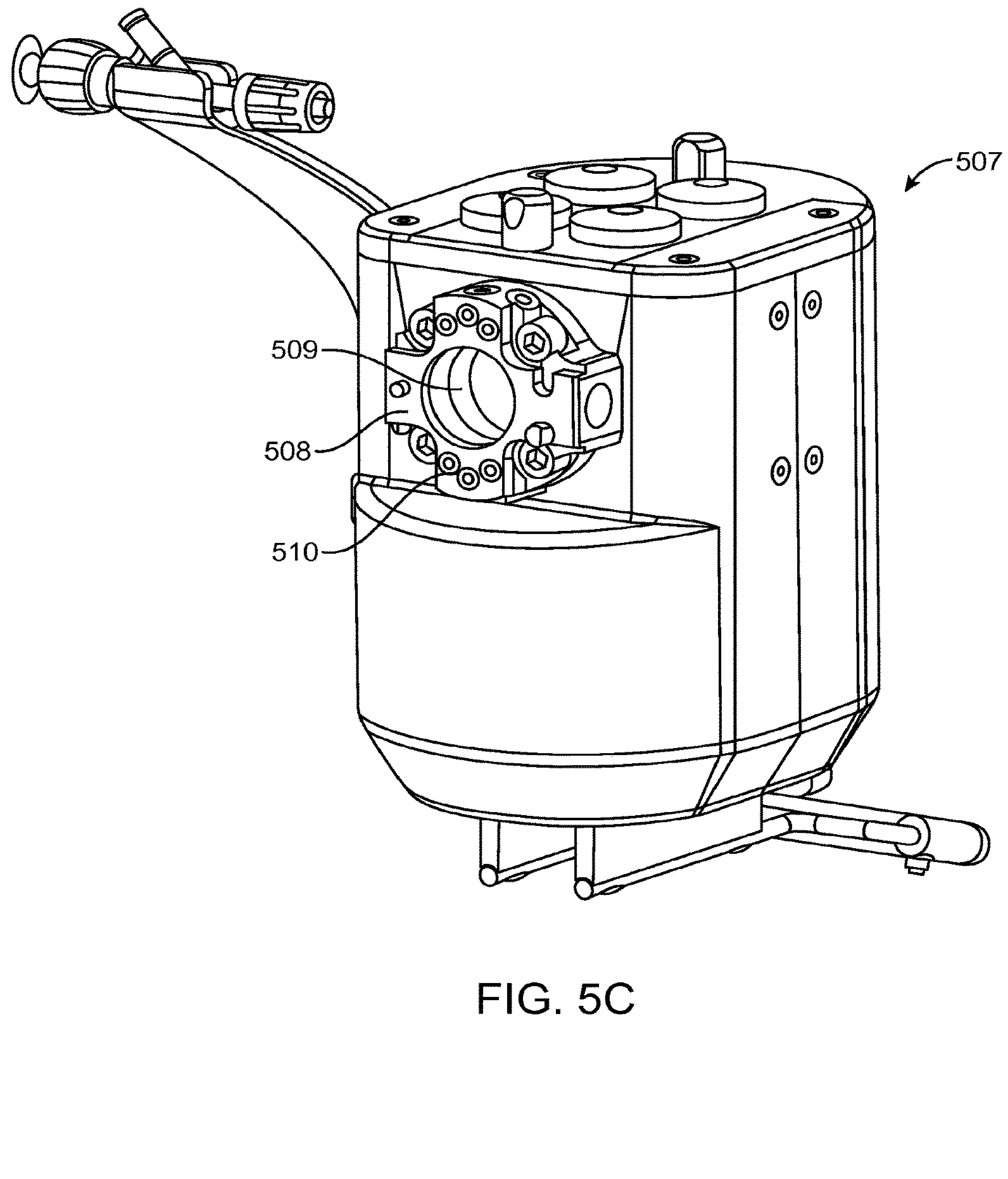


FIG. 5C

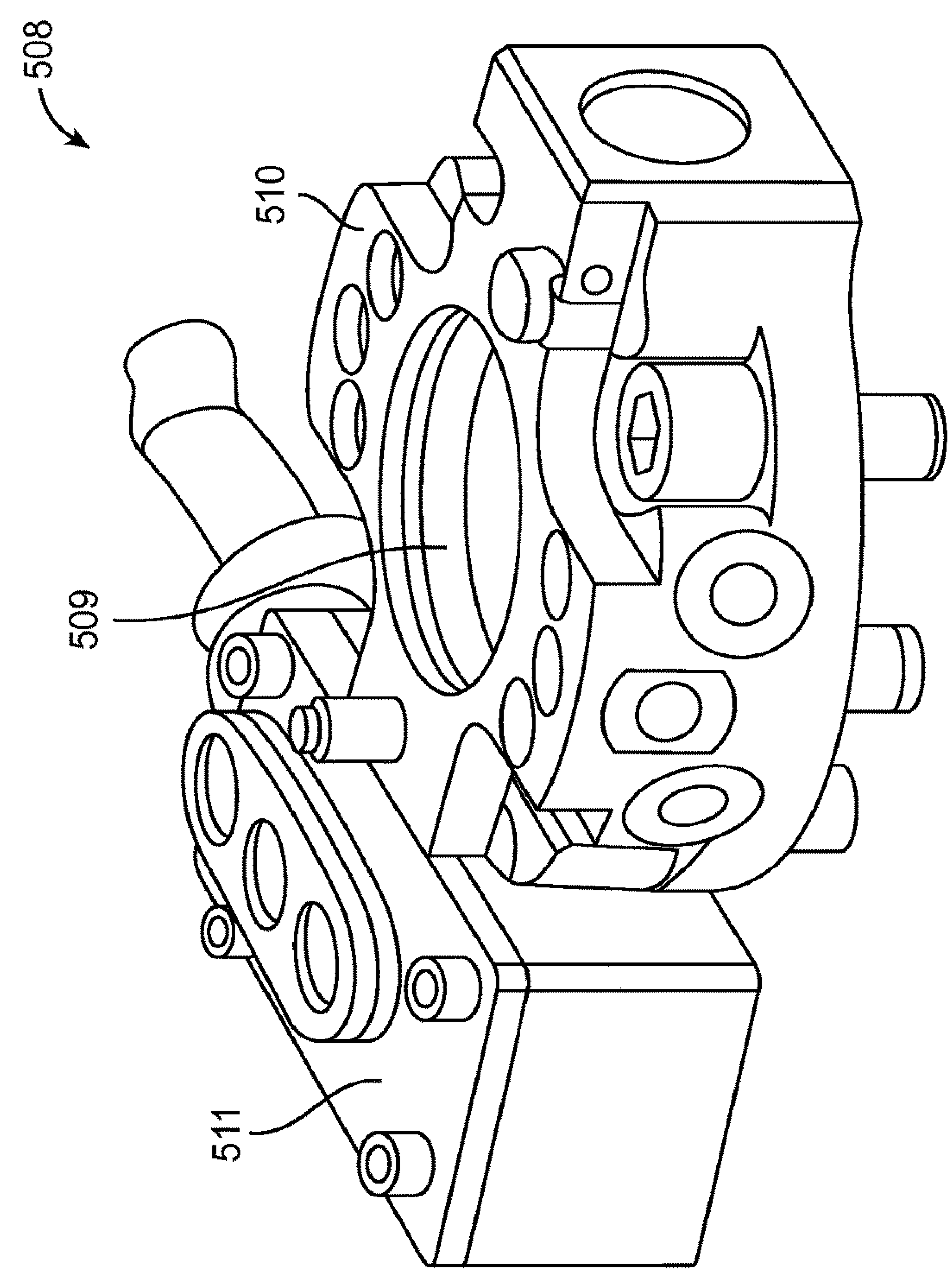


FIG. 5D

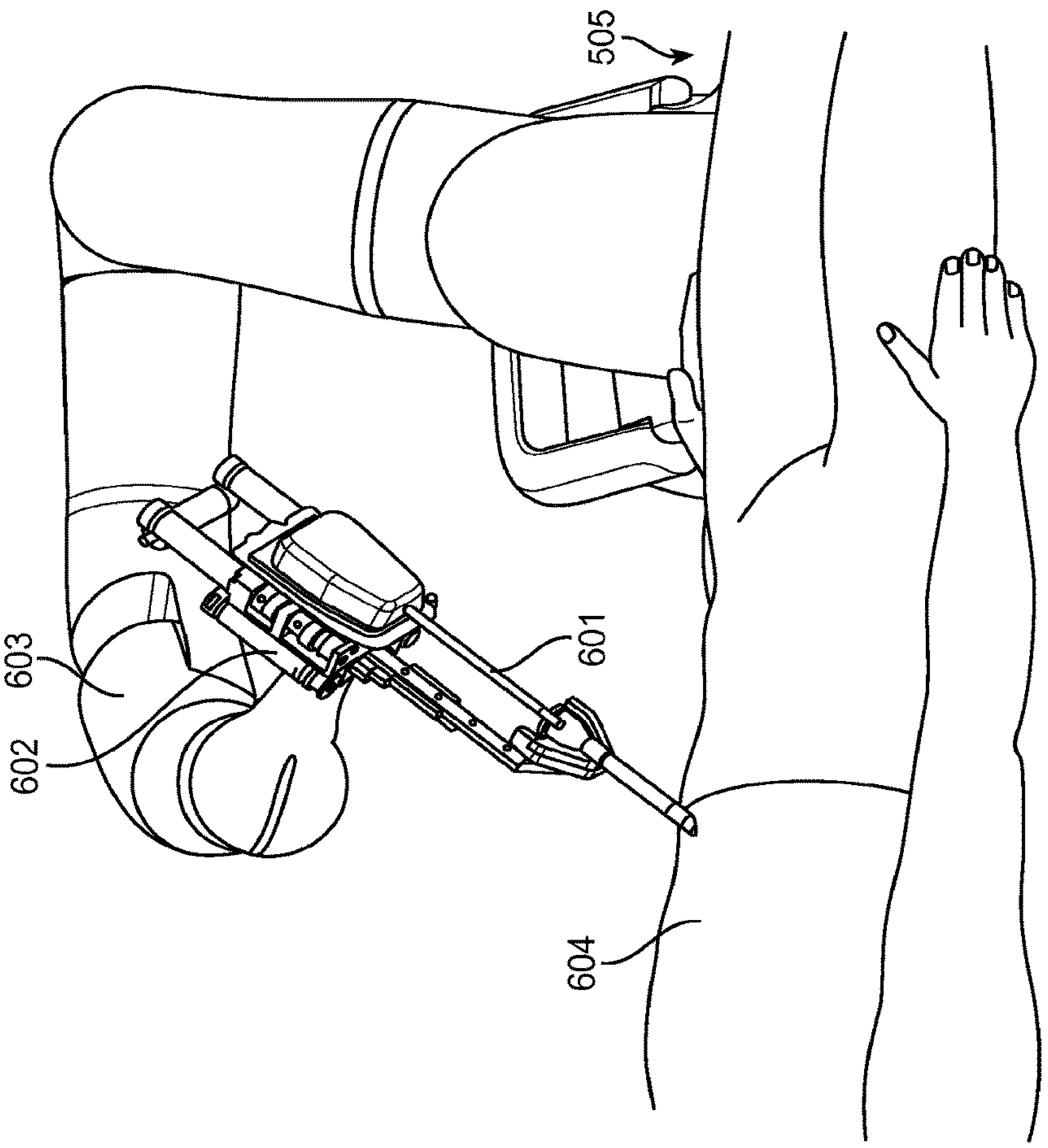


FIG. 6

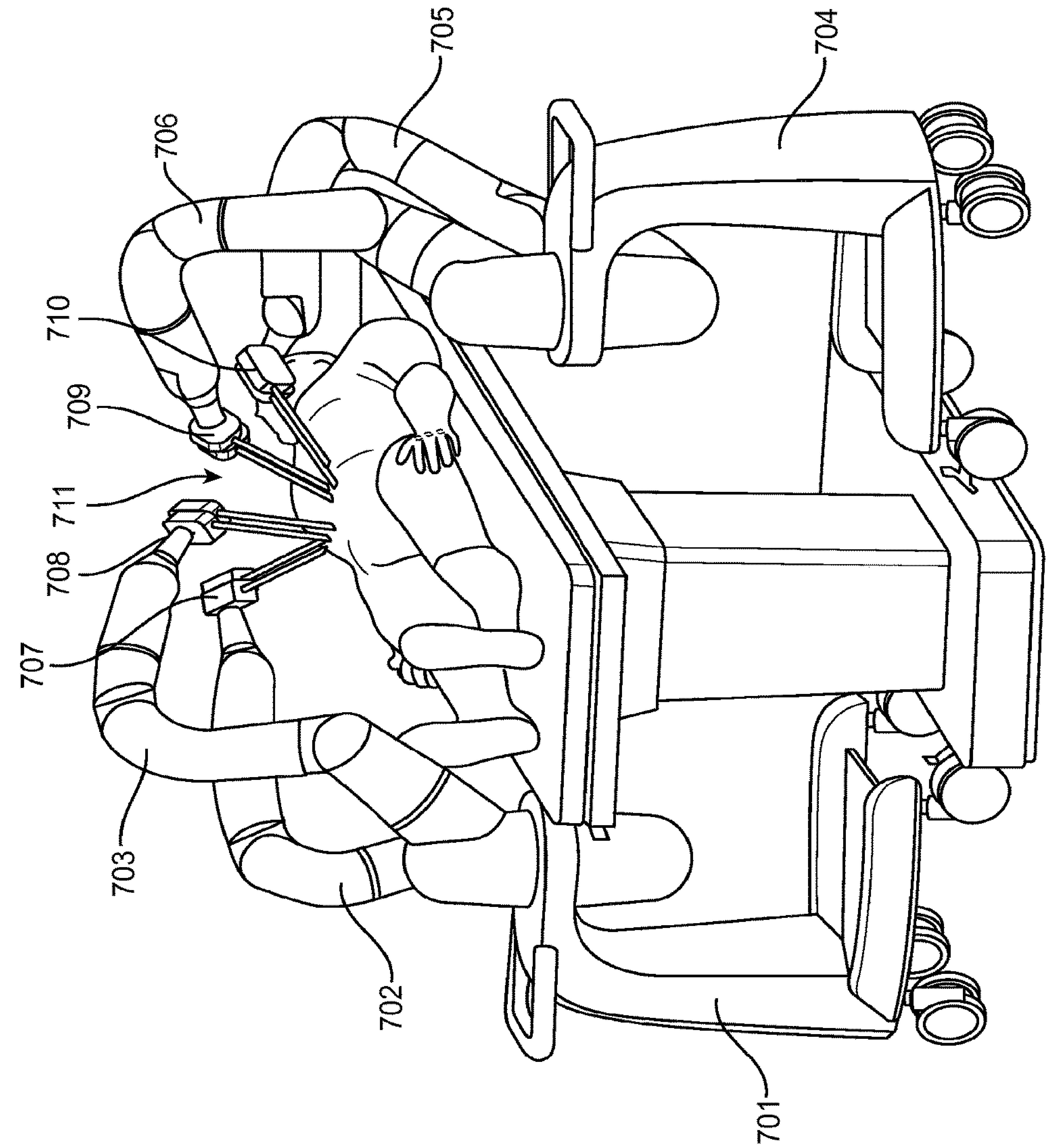


FIG. 7

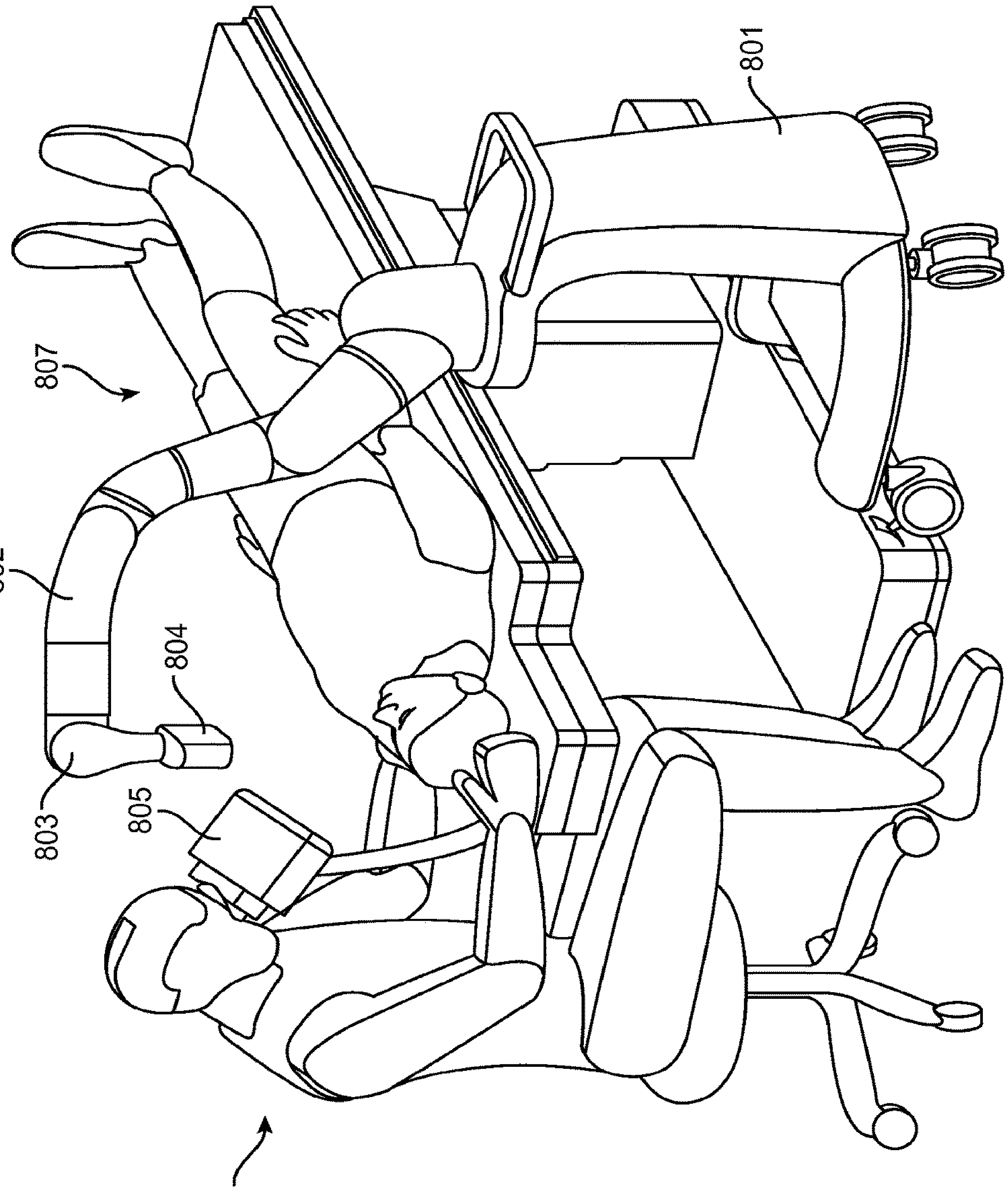


FIG. 8A

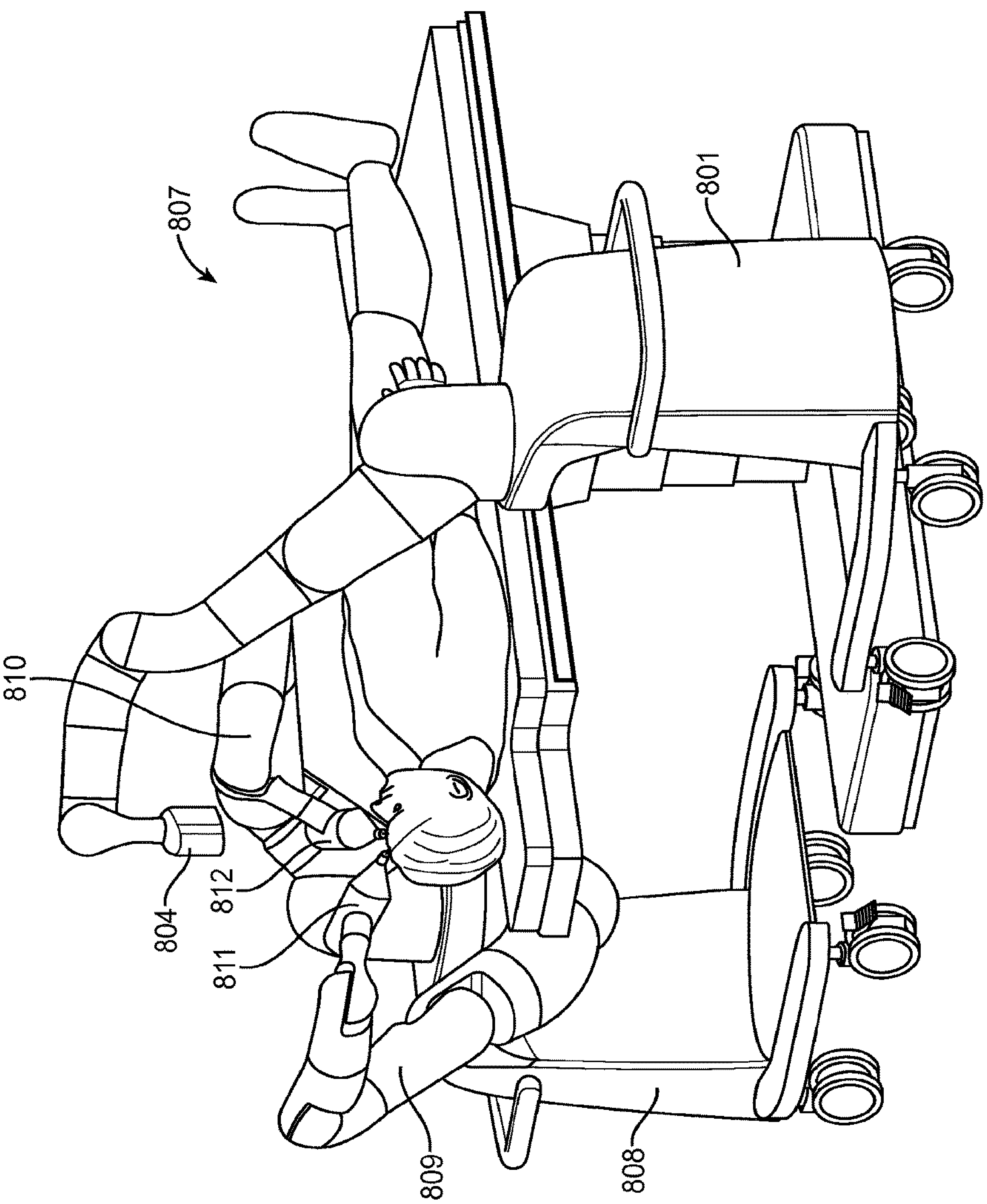


FIG. 8B

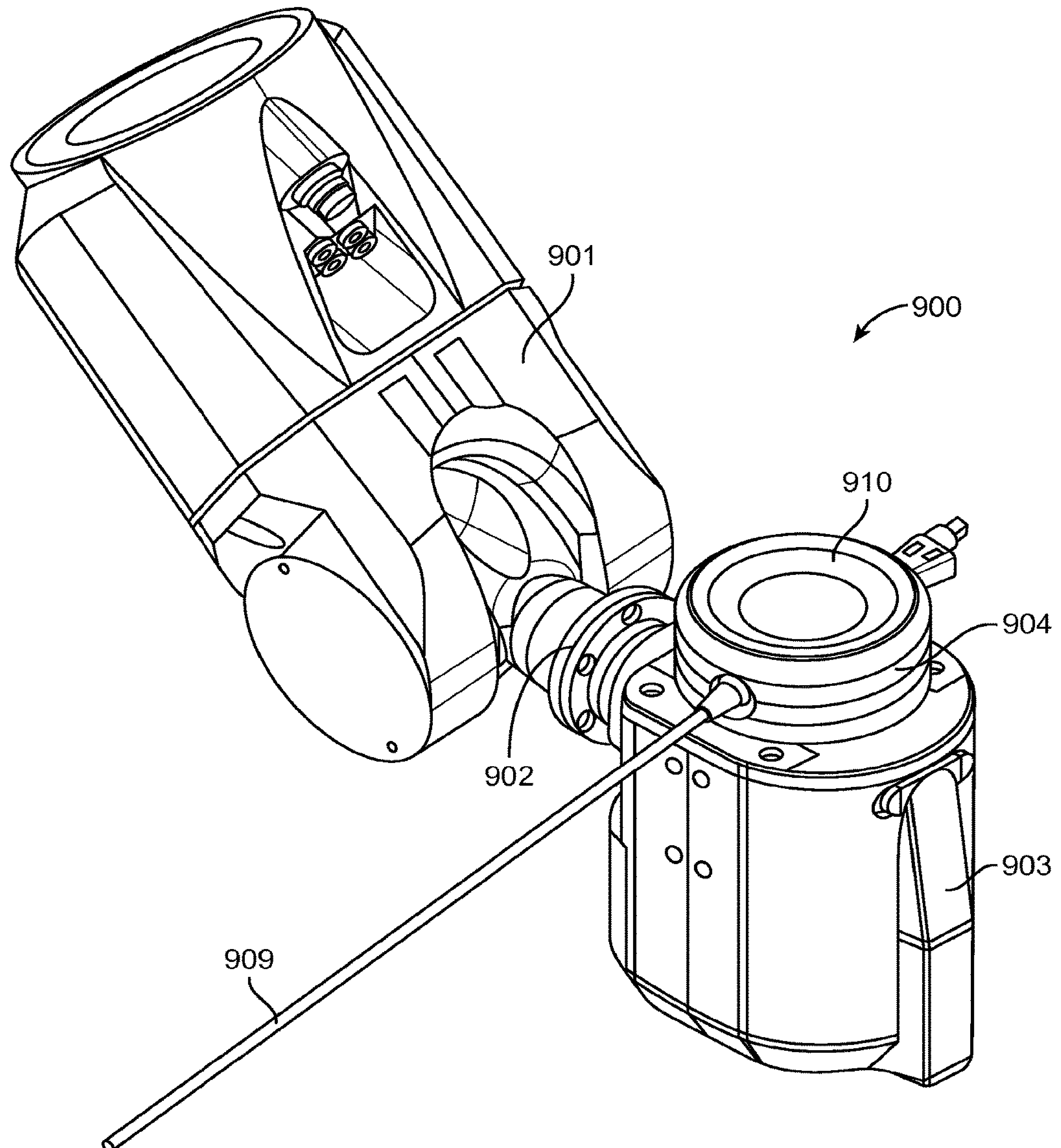


FIG. 9A

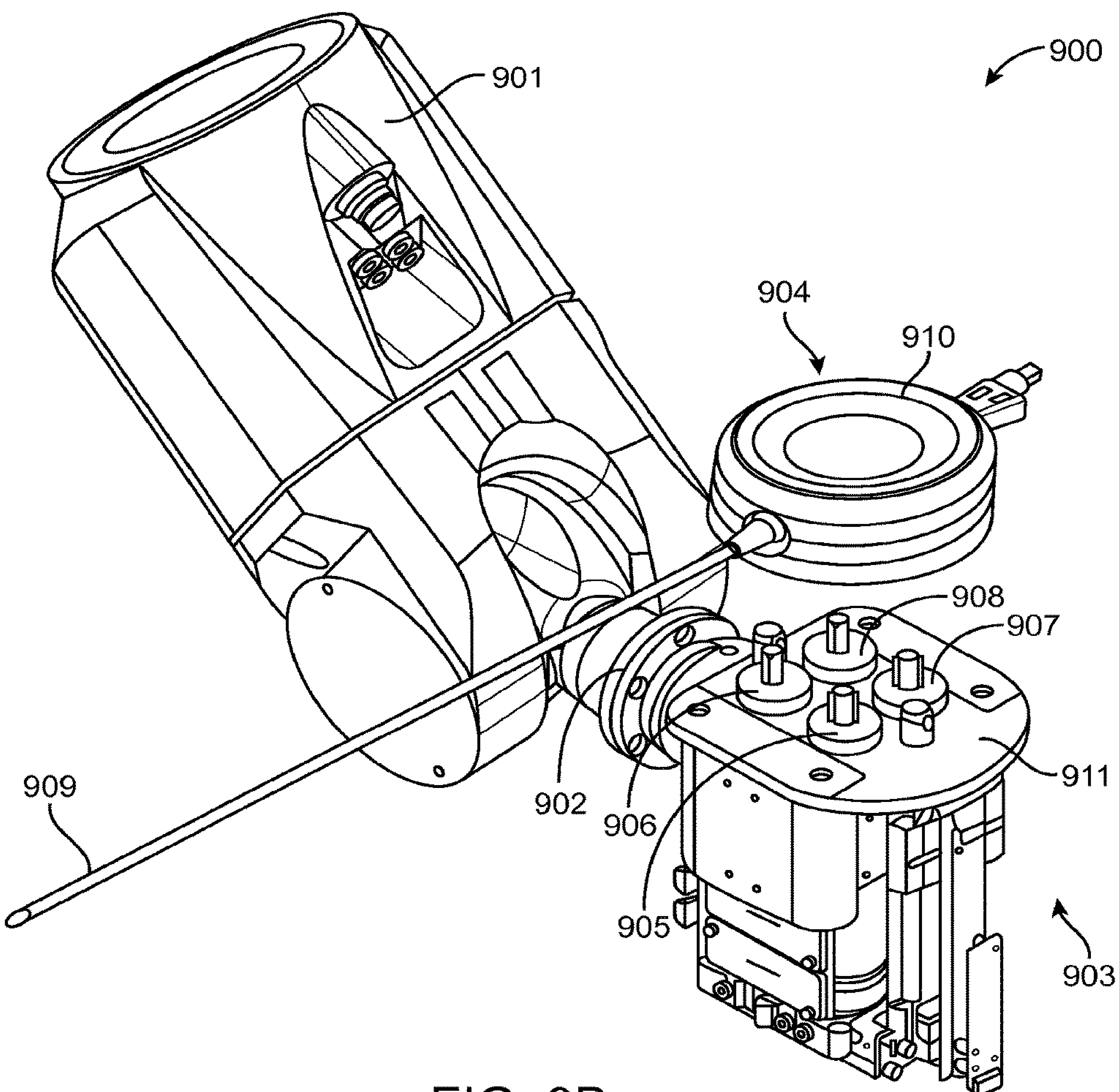


FIG. 9B

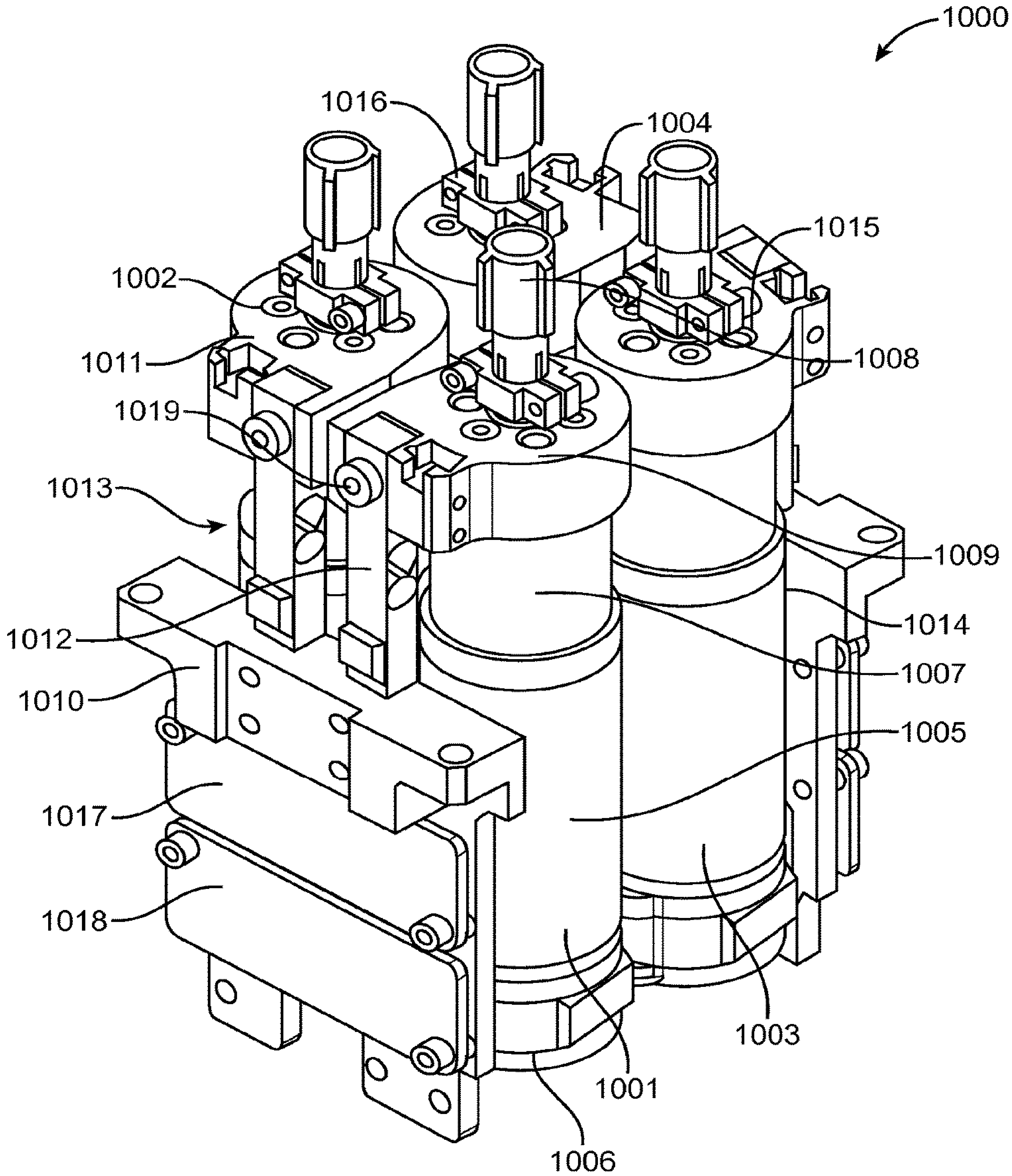

1000
1016
1004
1015
1002
1008
1011
1019
1013
1009
1012
1014
1007
1010
1005
1017
1018
1003
1001
1006

FIG. 10

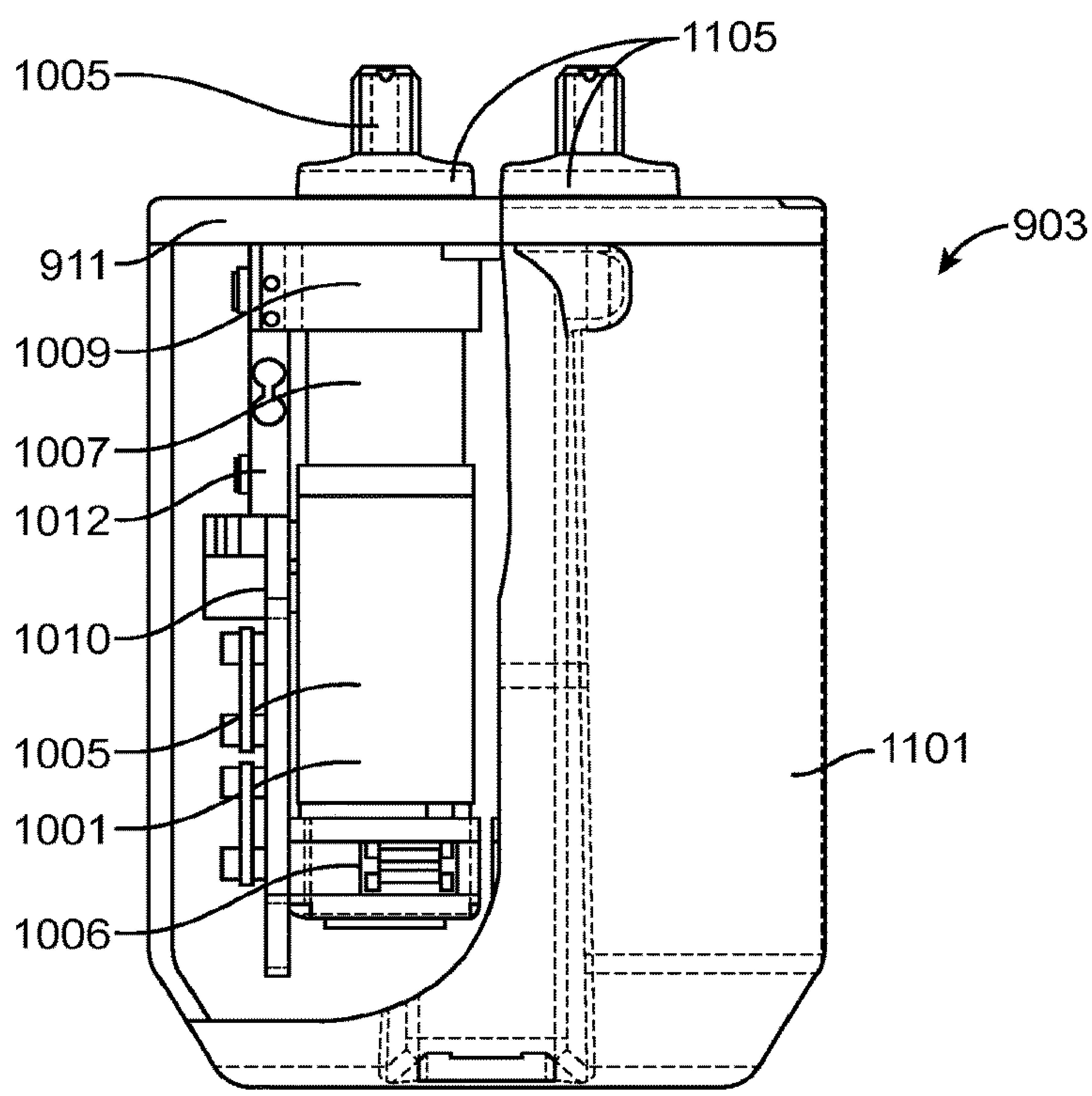
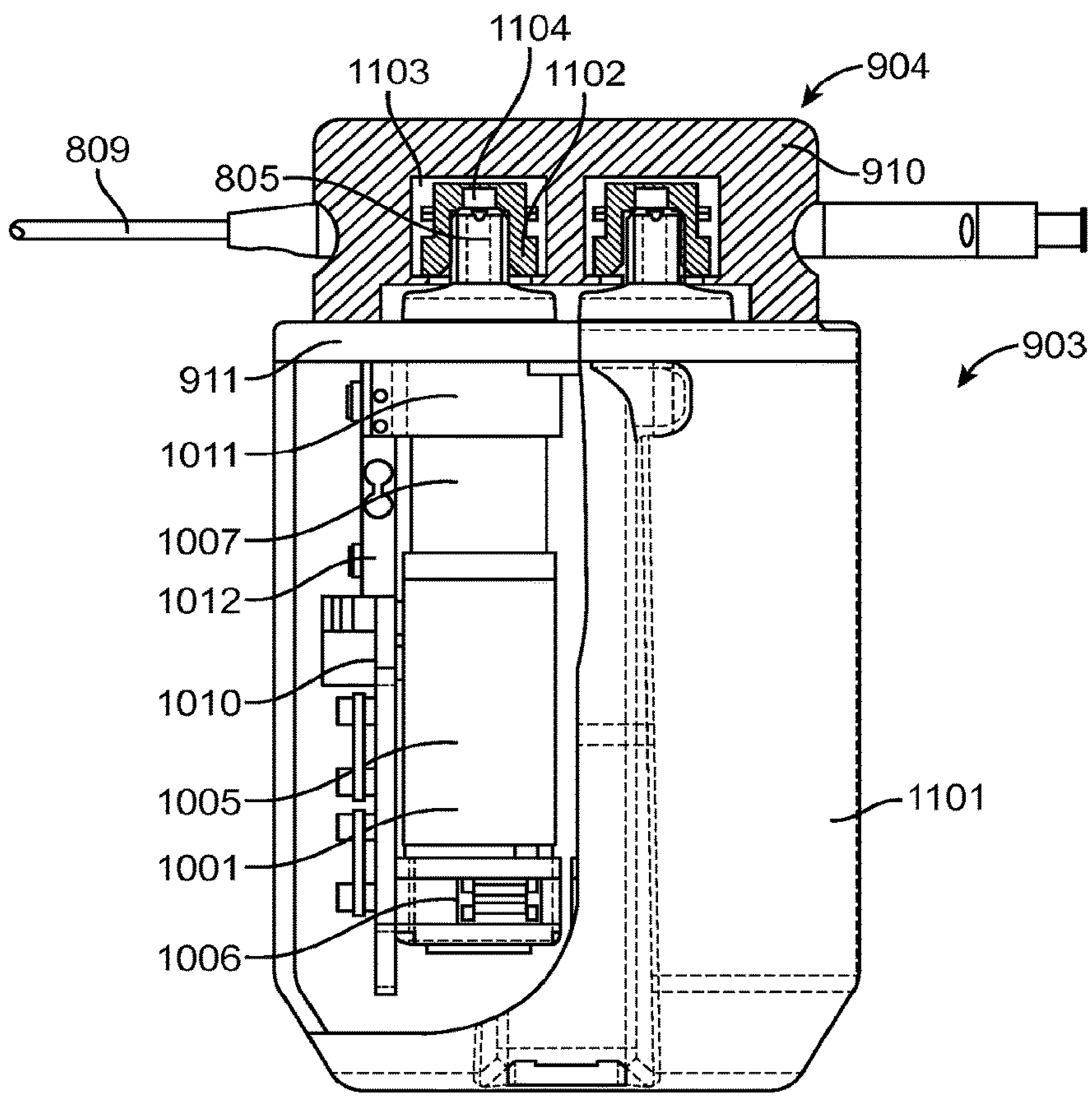


FIG. 11A


1104
1103
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904
809
805
910
903
911
1011
1007
1012
1010
1005
1101
1001
1006

FIG. 11B

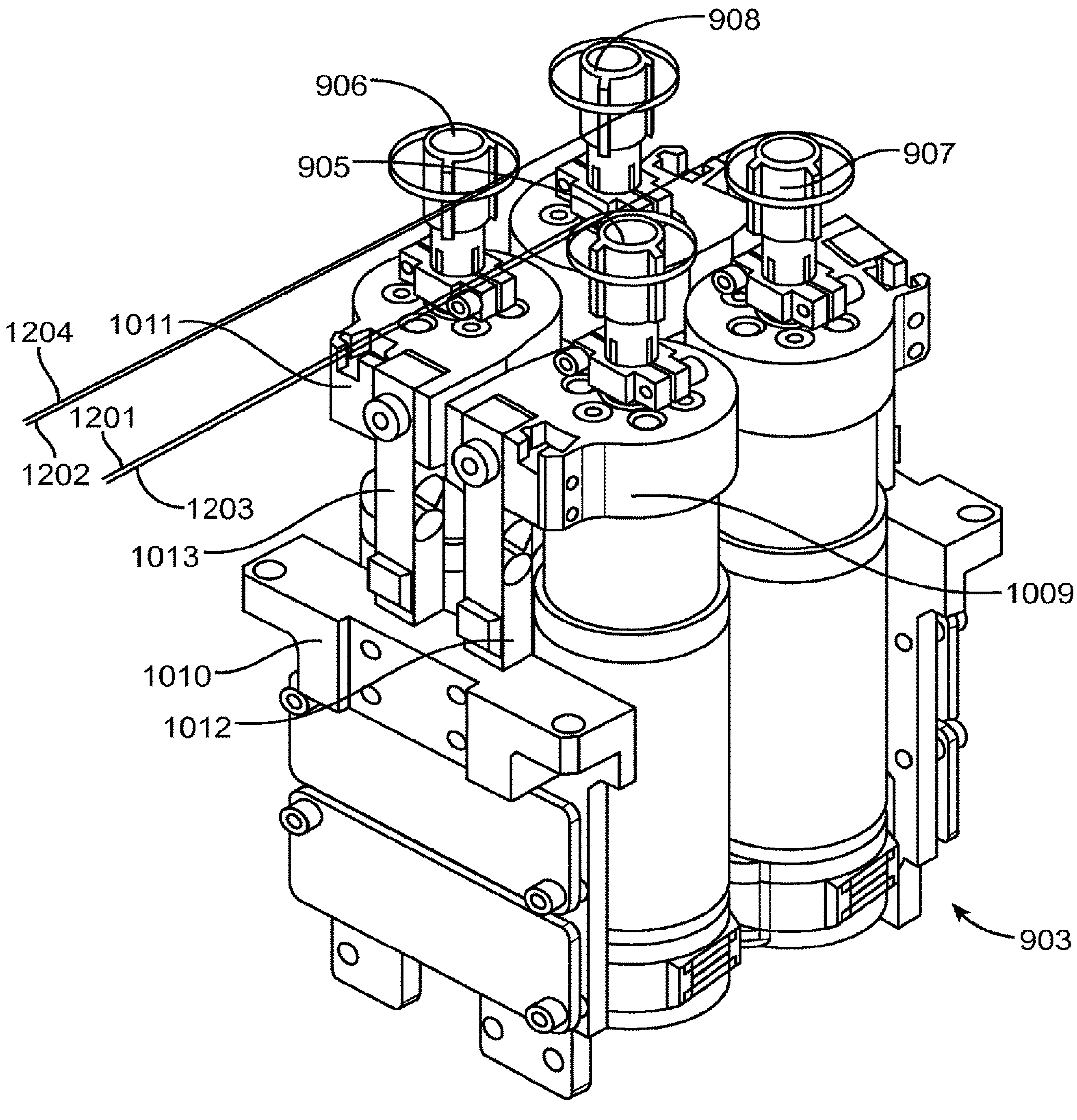

908
906
905
907
1204
1011
1201
1202
1203
1013
1009
1010
1012
903

FIG. 12

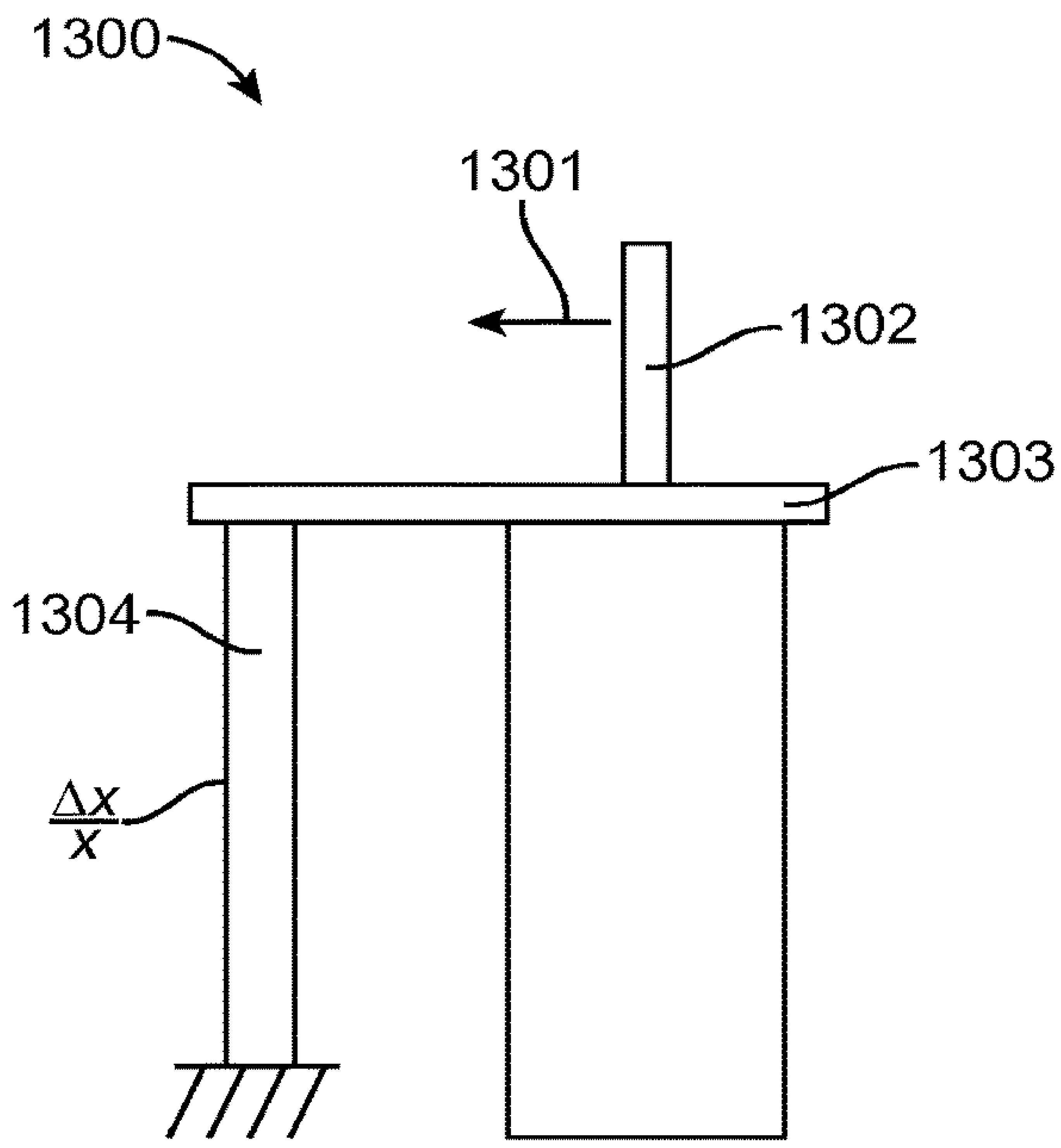


FIG. 13

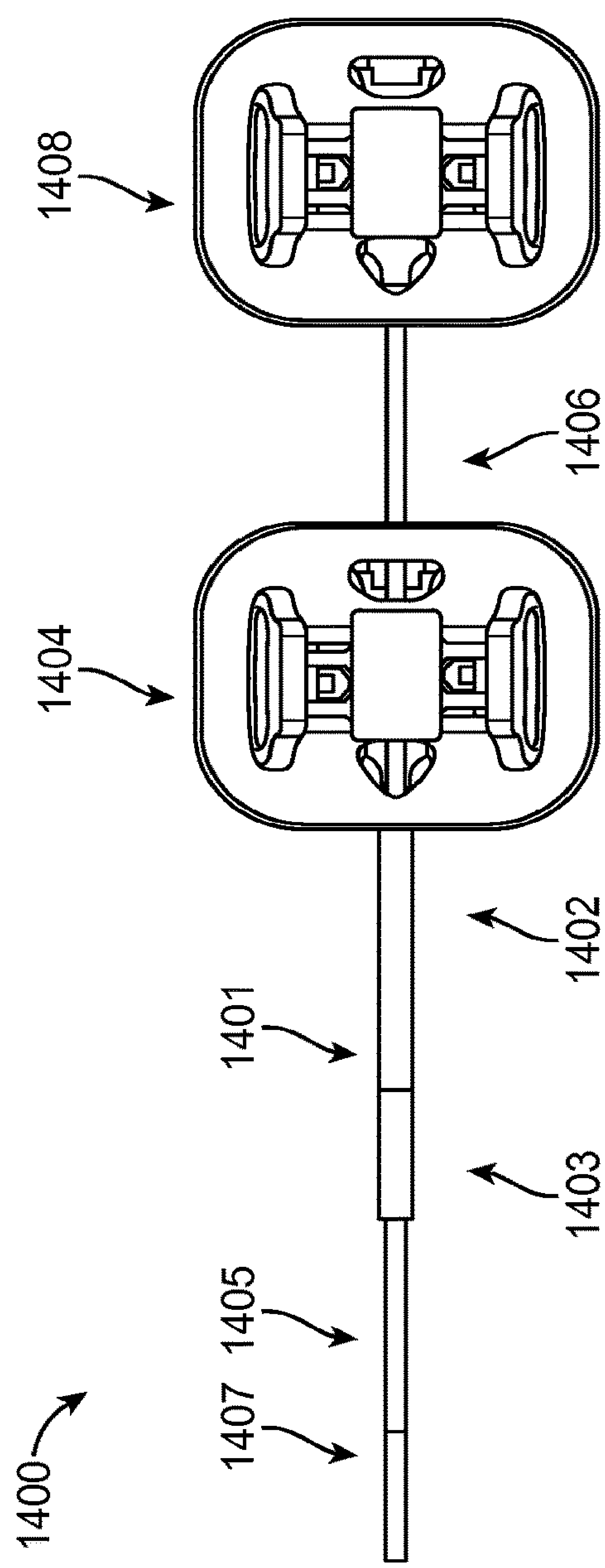


FIG. 14

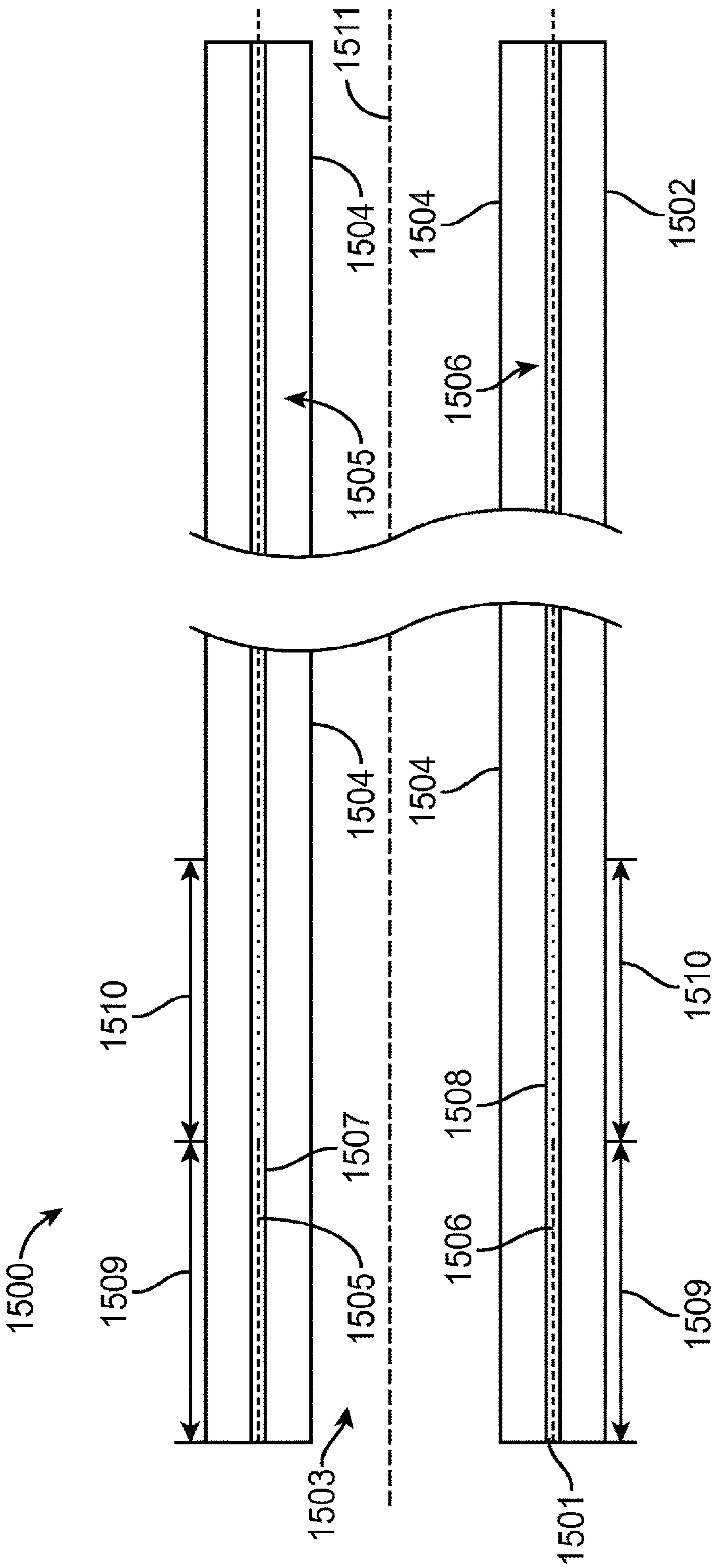


FIG. 15A

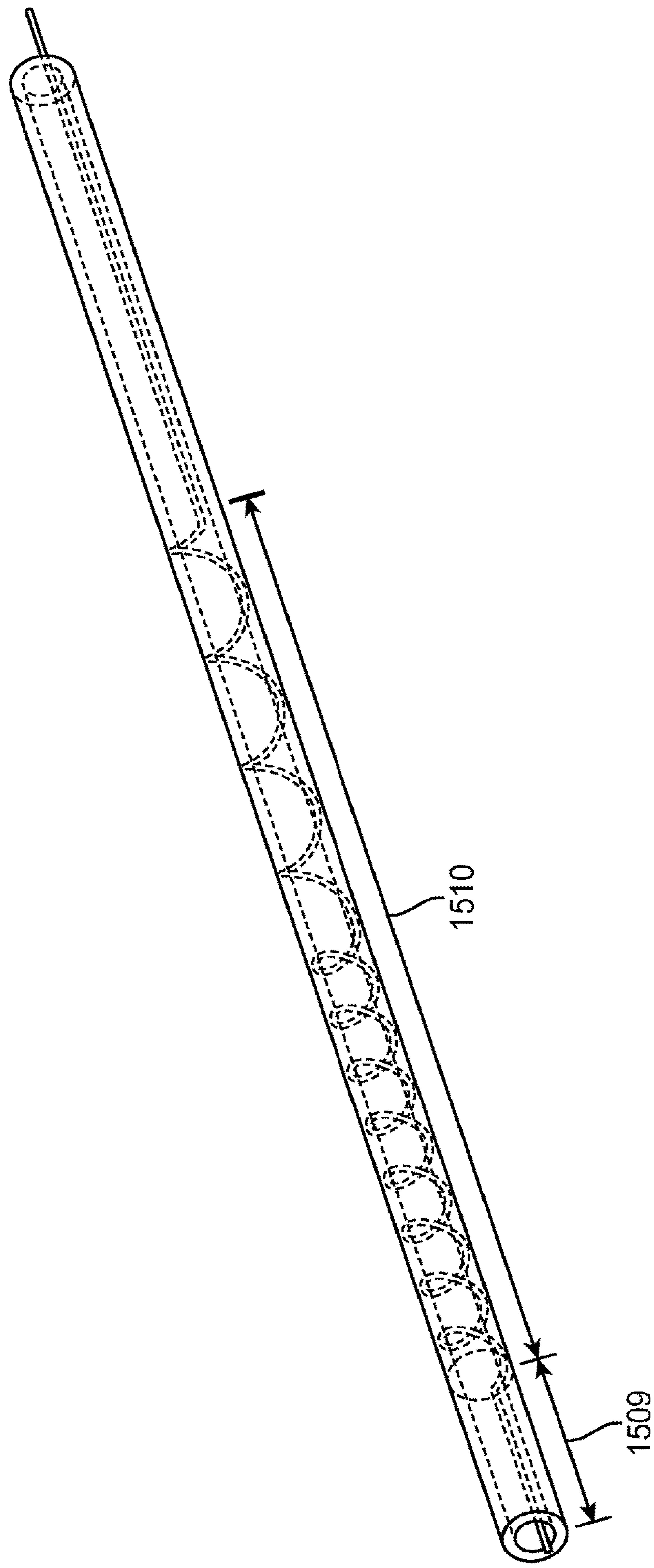


FIG. 15B

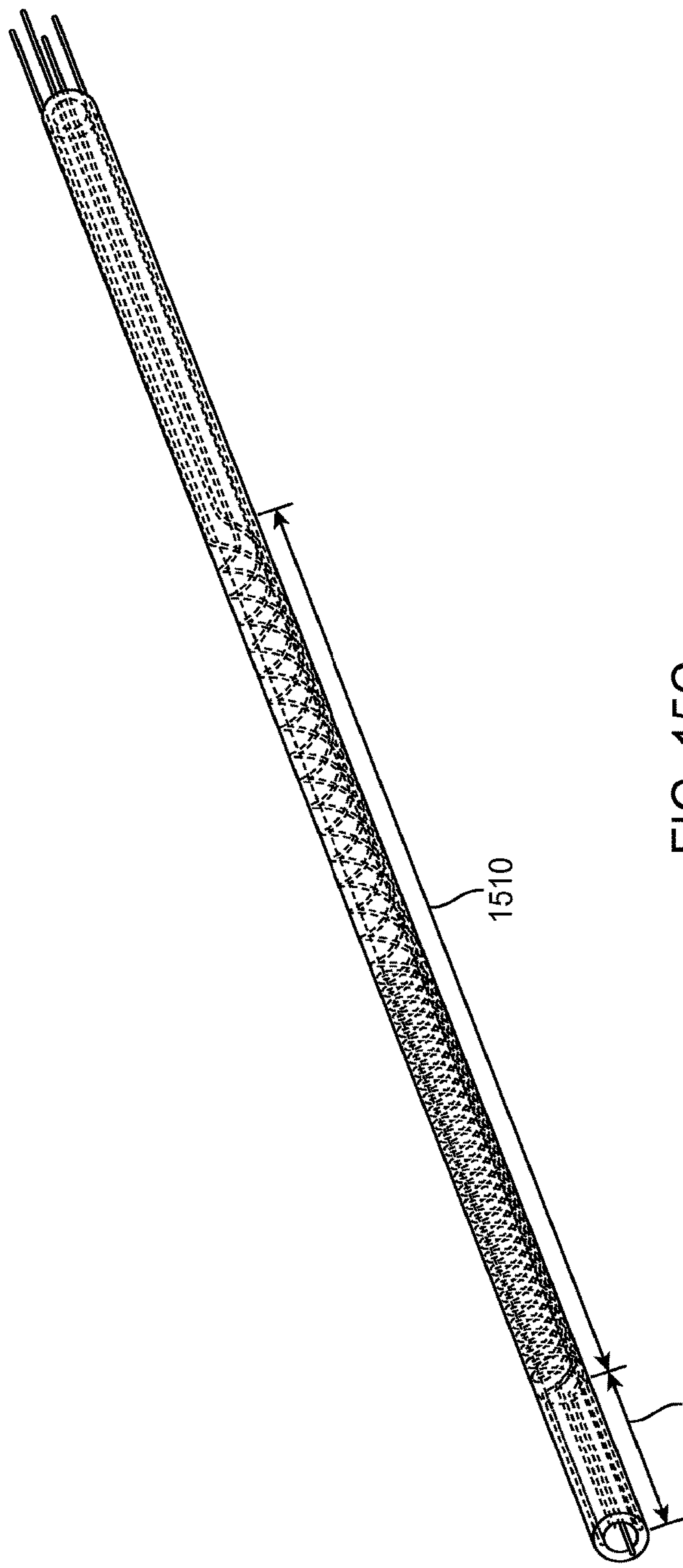


FIG. 15C

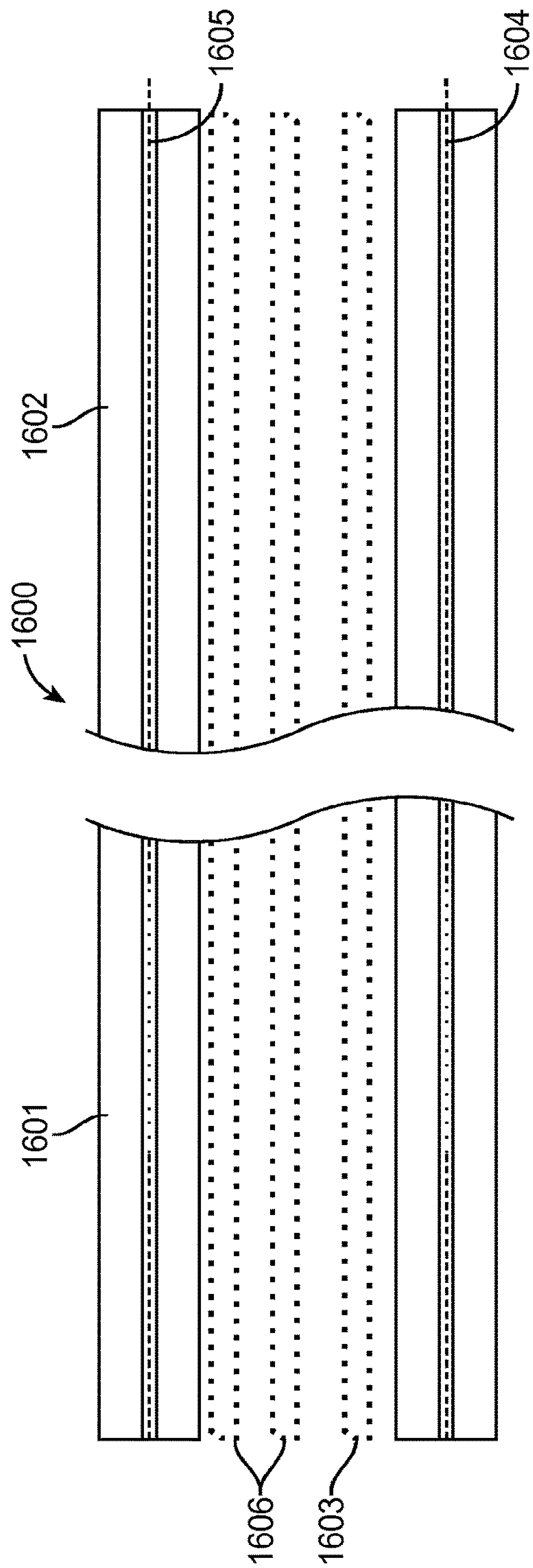


FIG. 16A

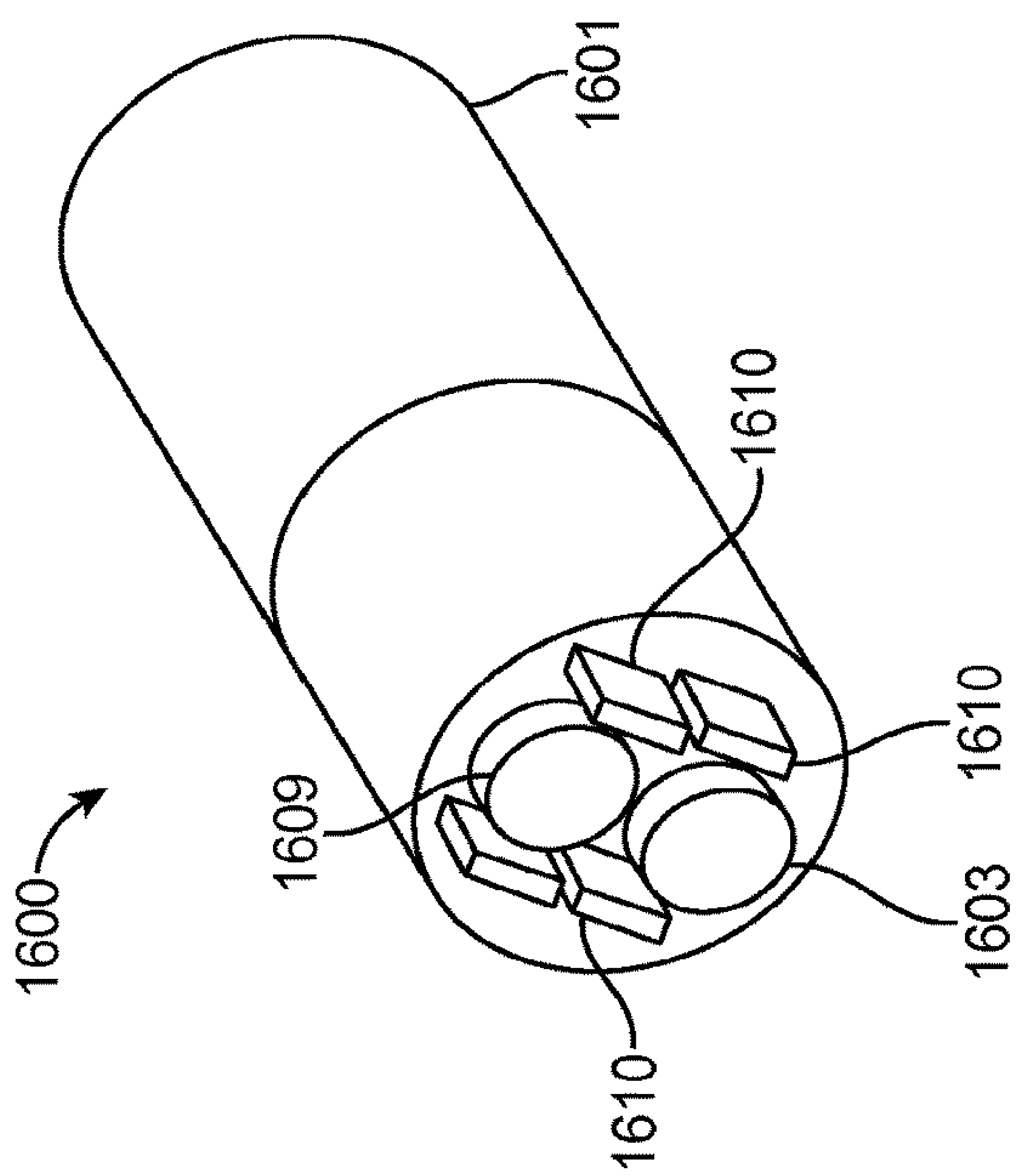


FIG. 16B

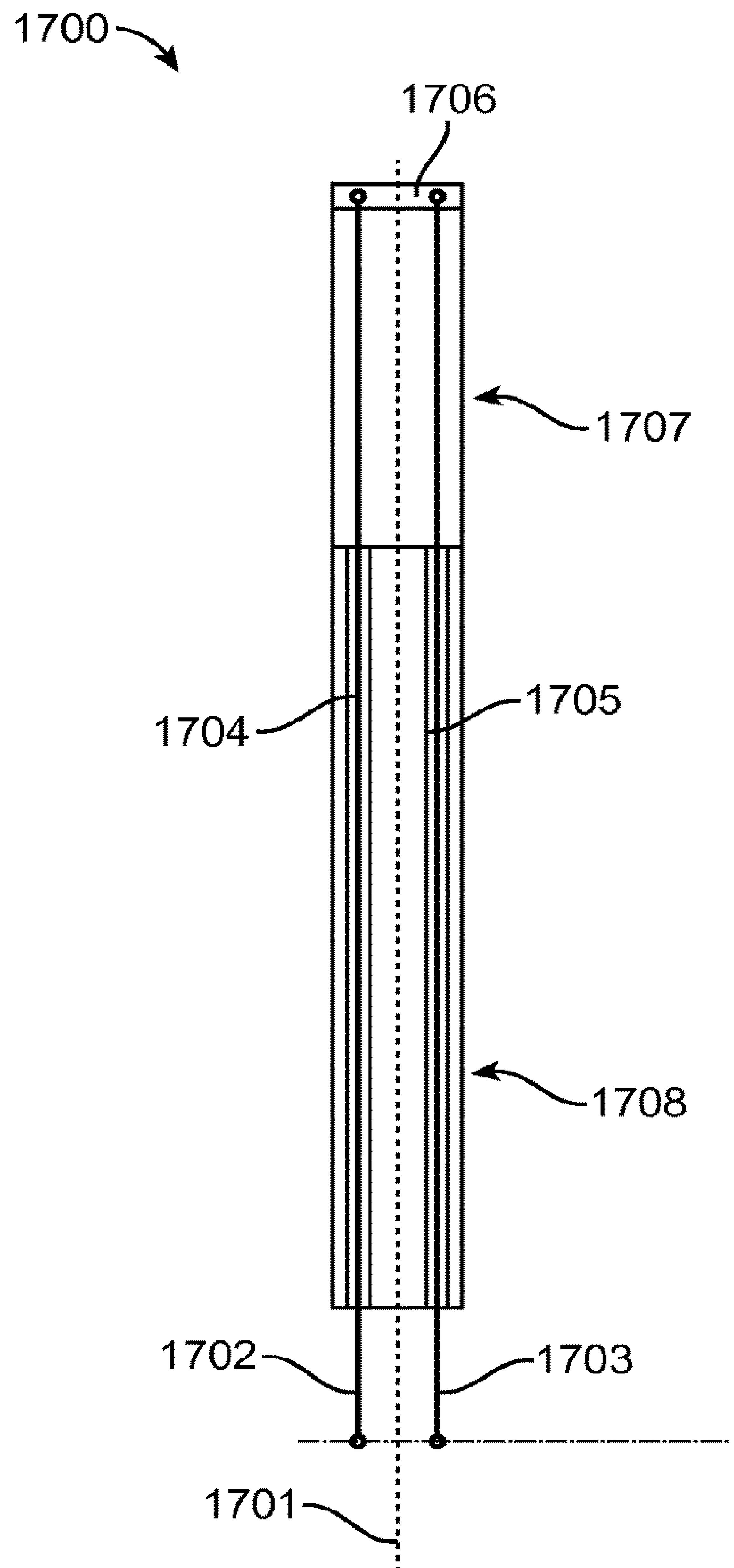


FIG. 17A
(PRIOR ART)

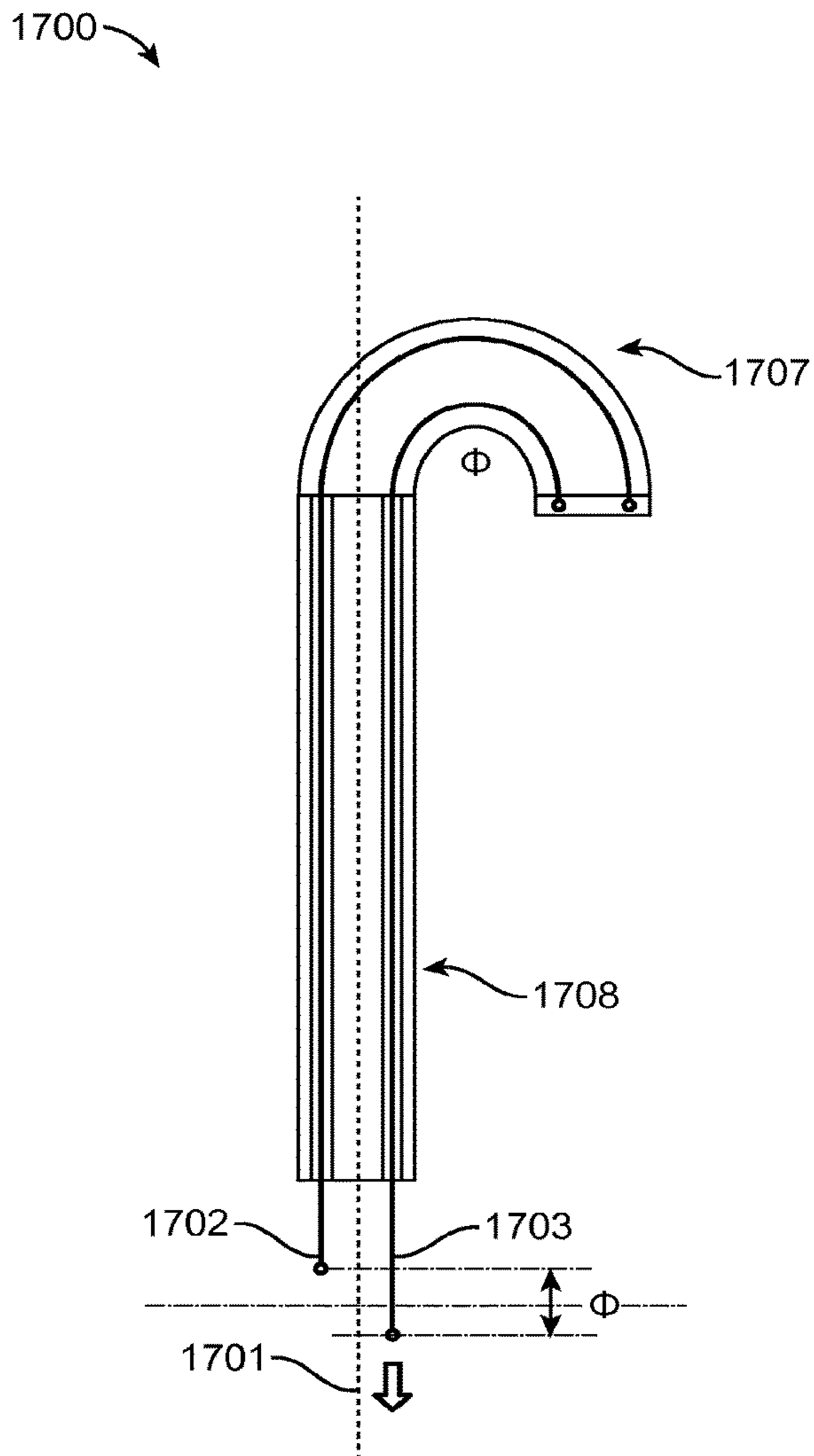


FIG. 17B
(PRIOR ART)

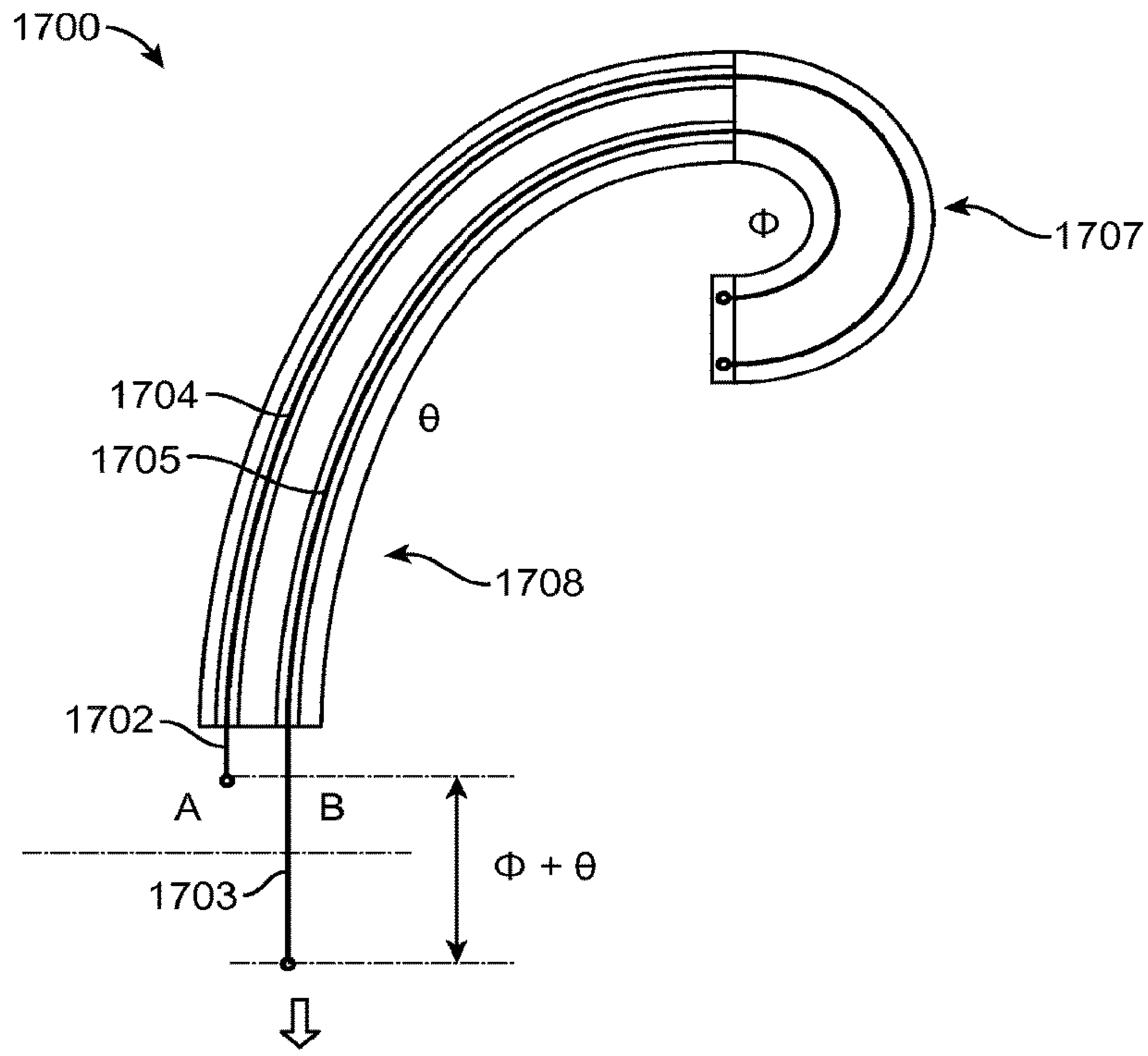


FIG. 17C
(PRIOR ART)

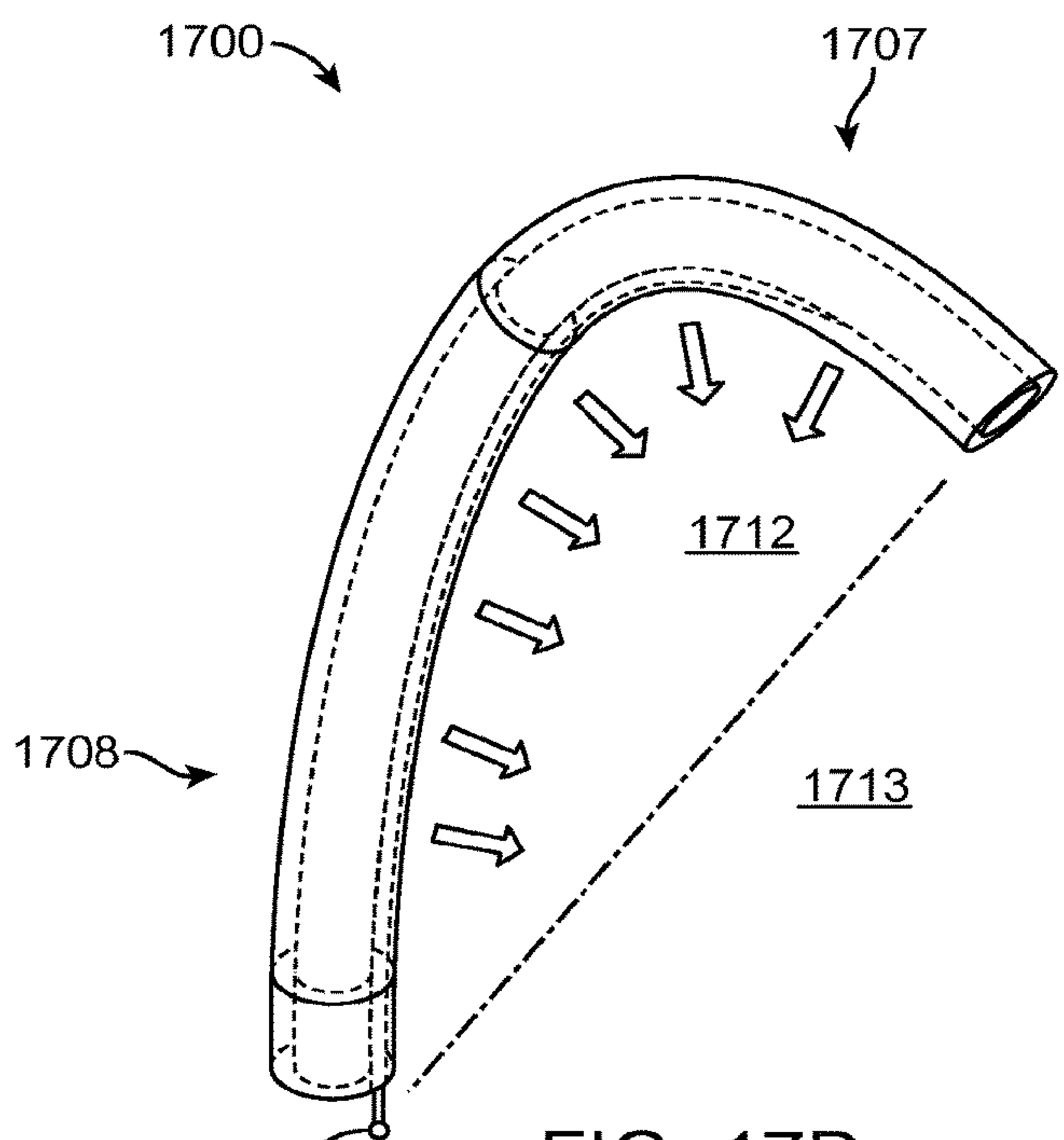


FIG. 17D
(PRIOR ART)

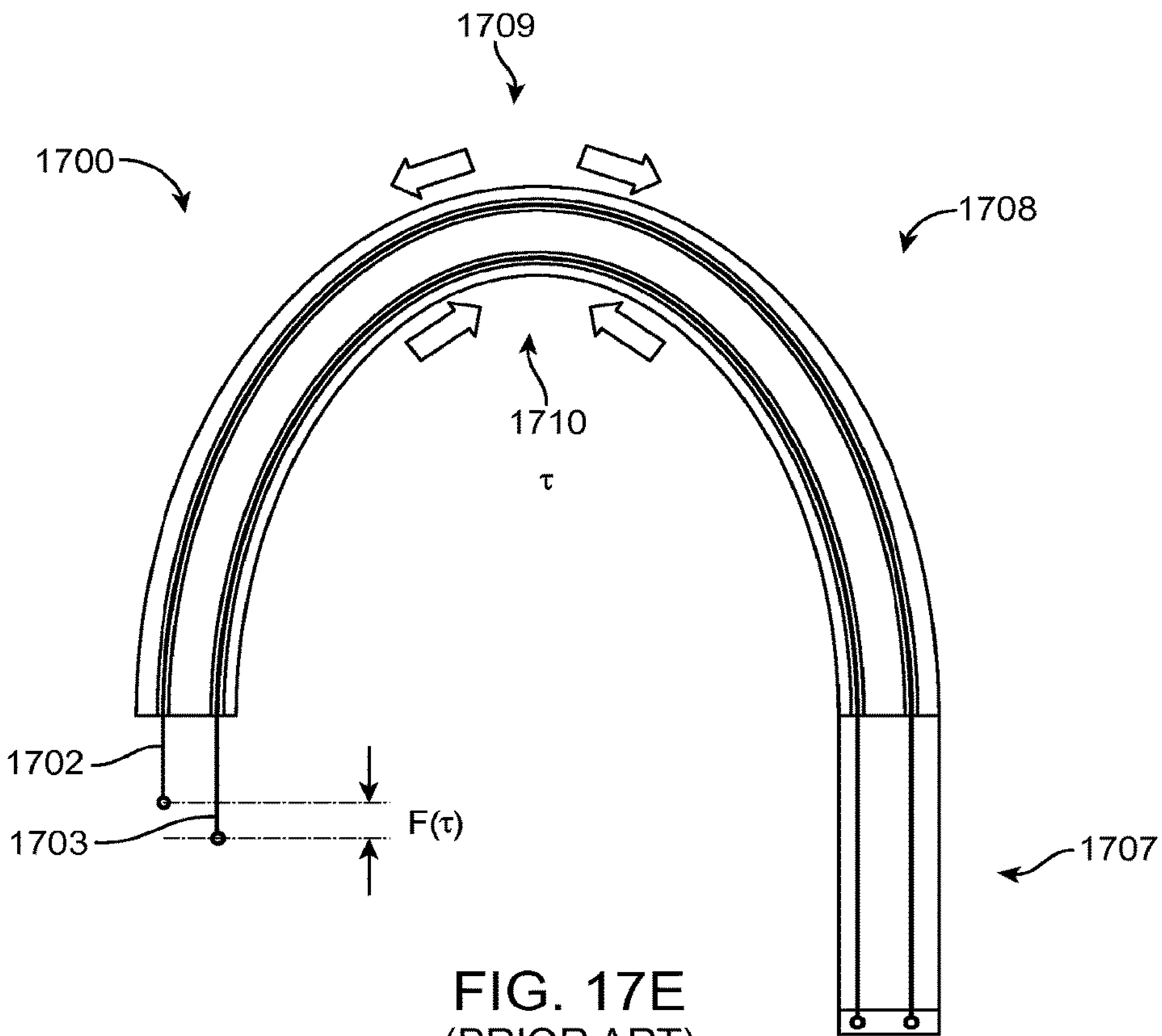


FIG. 17E
(PRIOR ART)

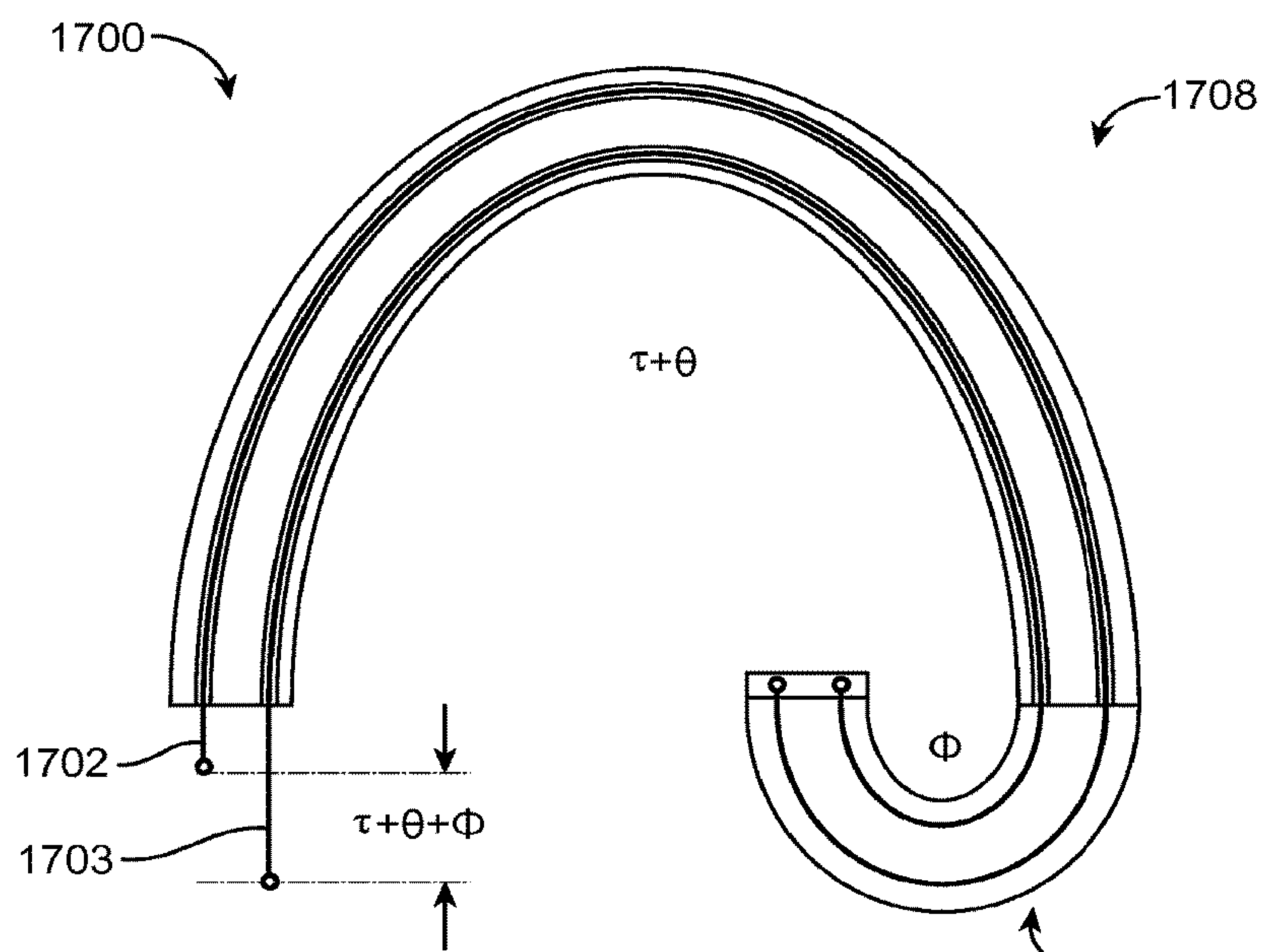


FIG. 17F
(PRIOR ART)

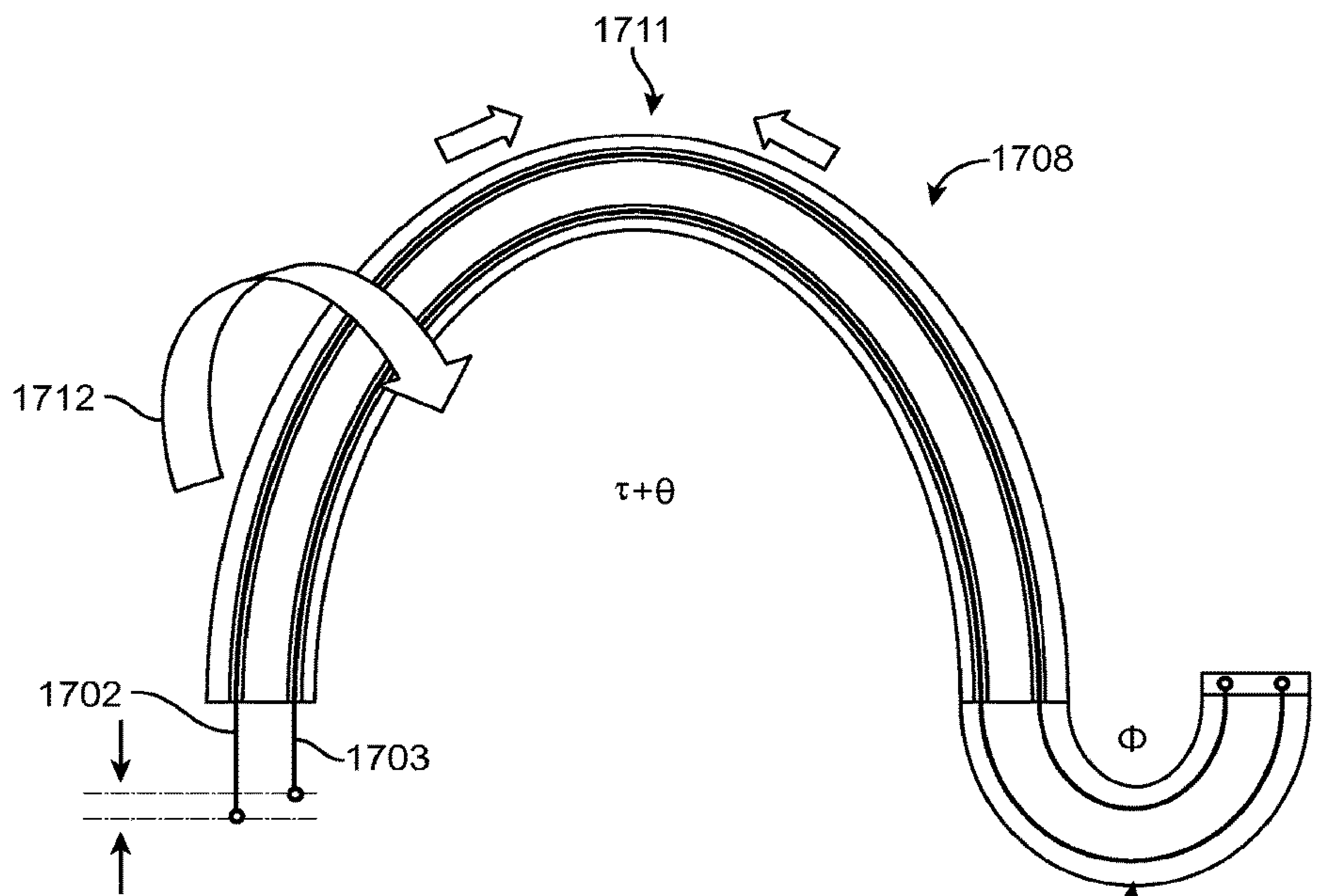


FIG. 17G
(PRIOR ART)

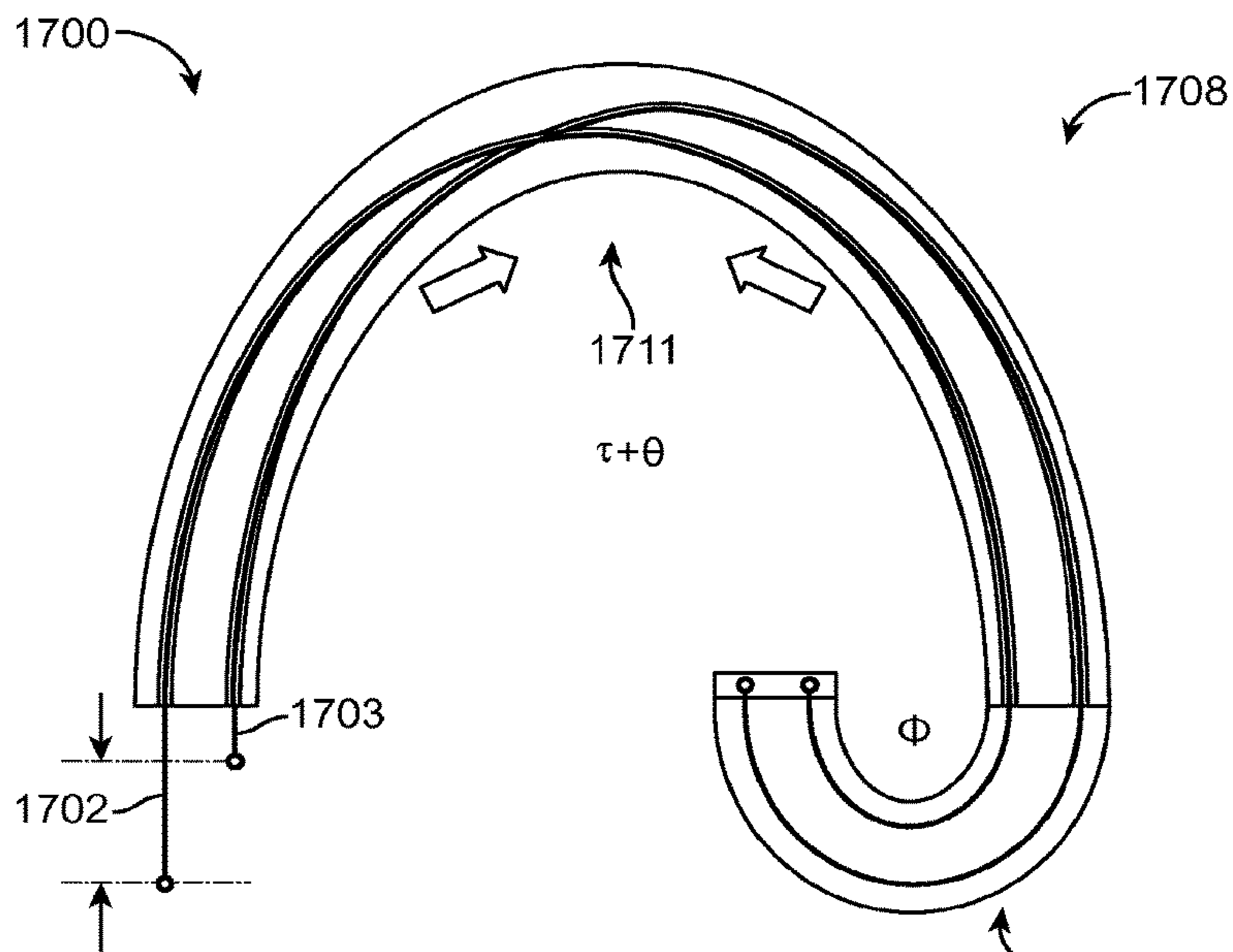


FIG. 17H
(PRIOR ART)

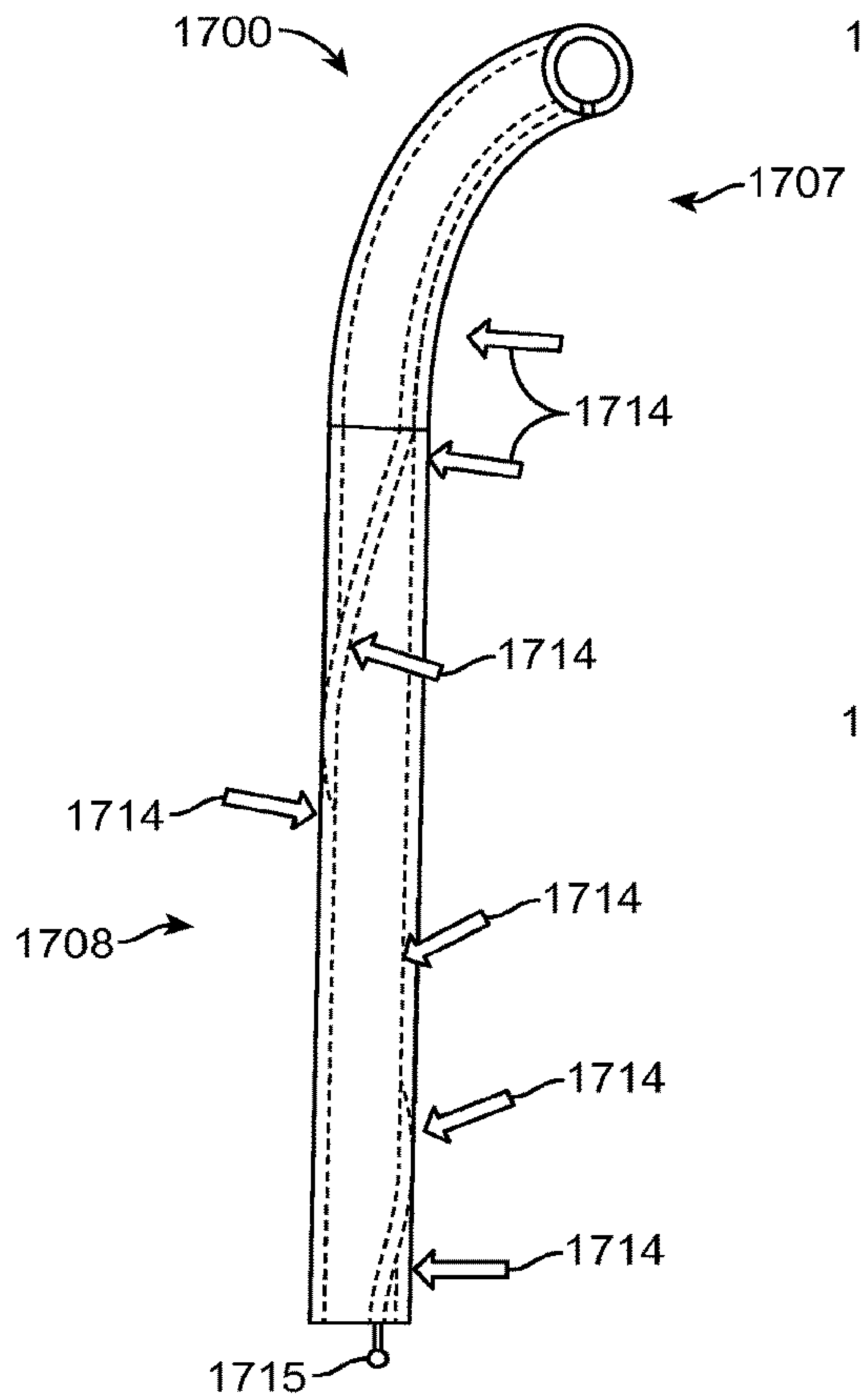


FIG. 17I

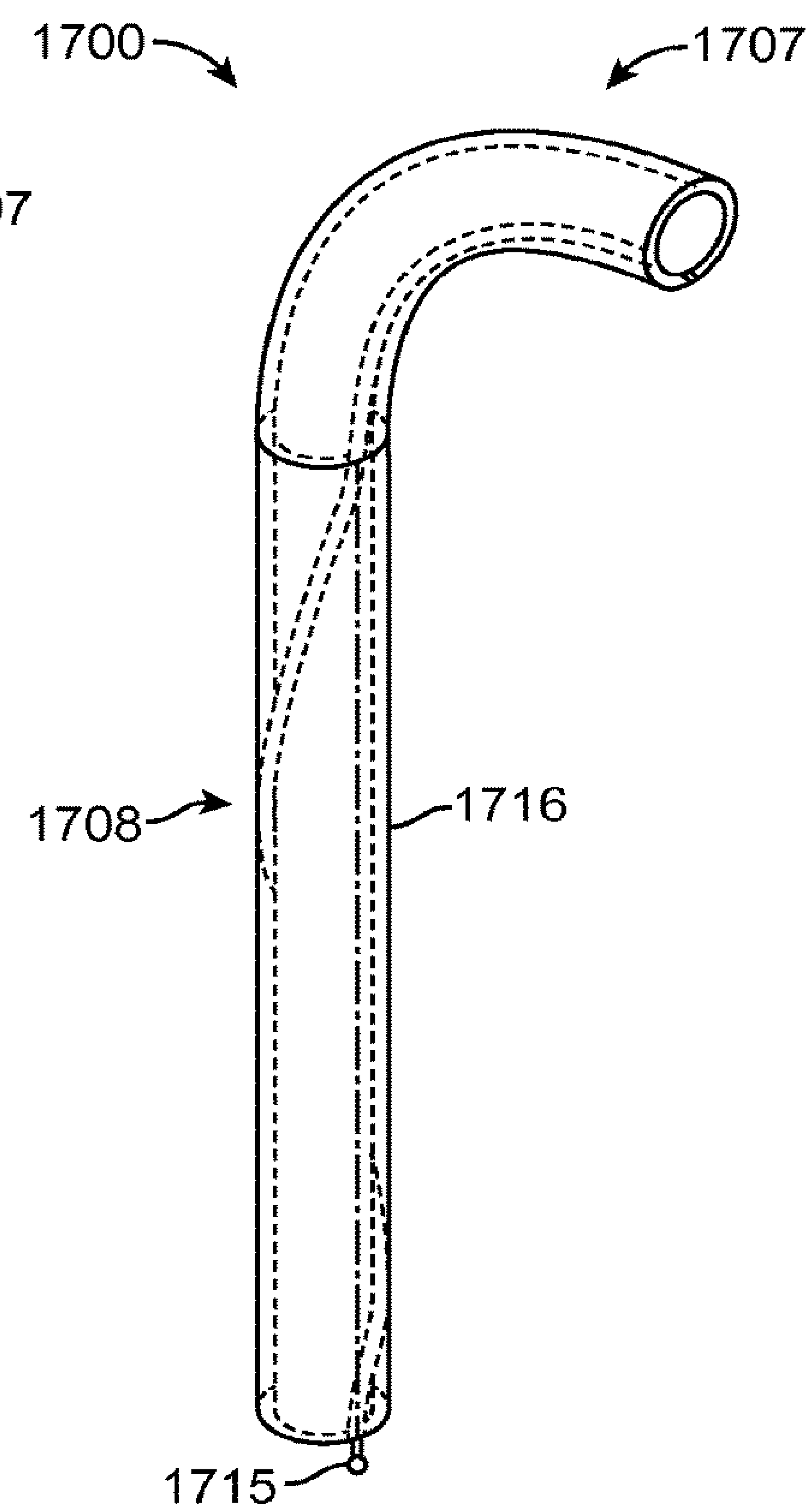


FIG. 17J

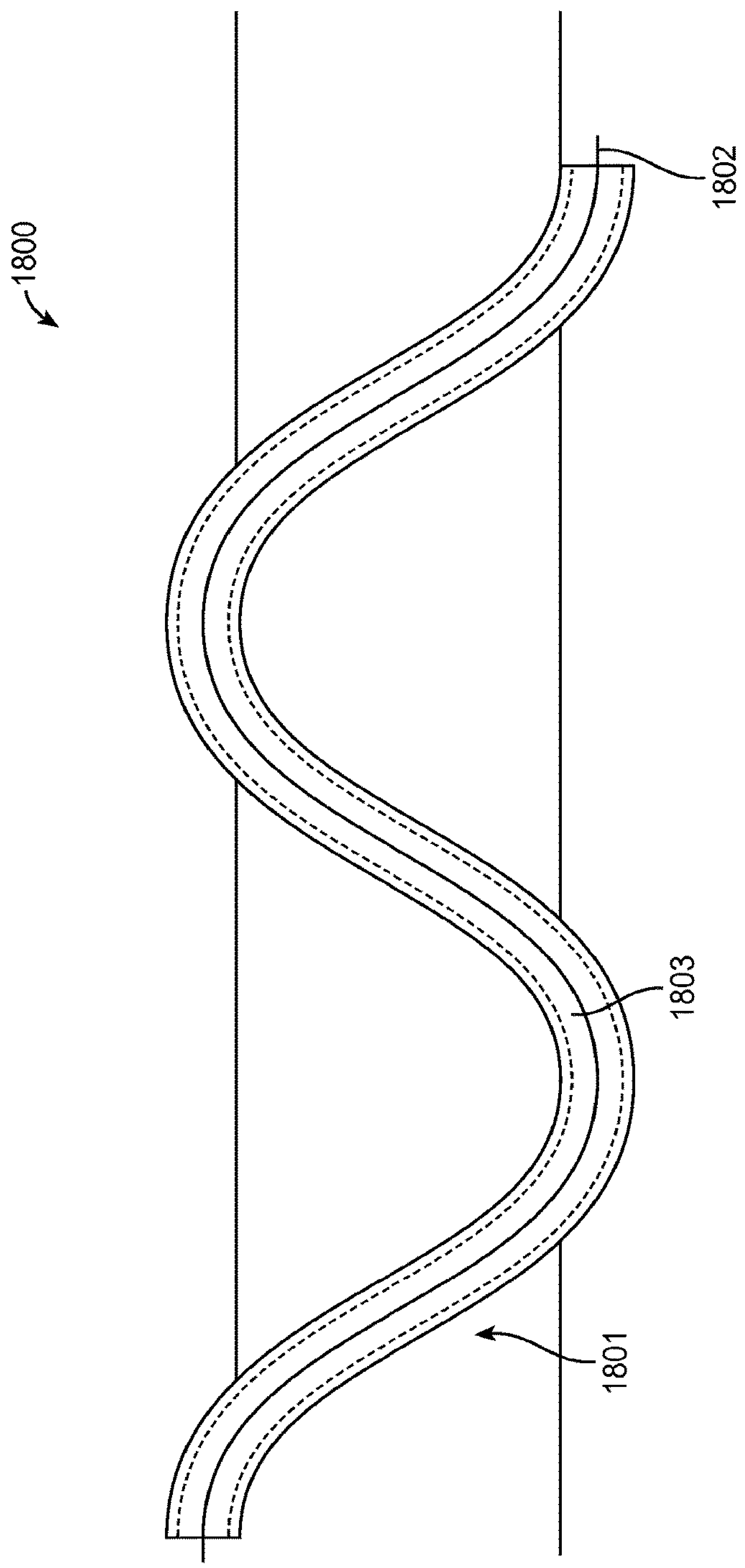


FIG. 18

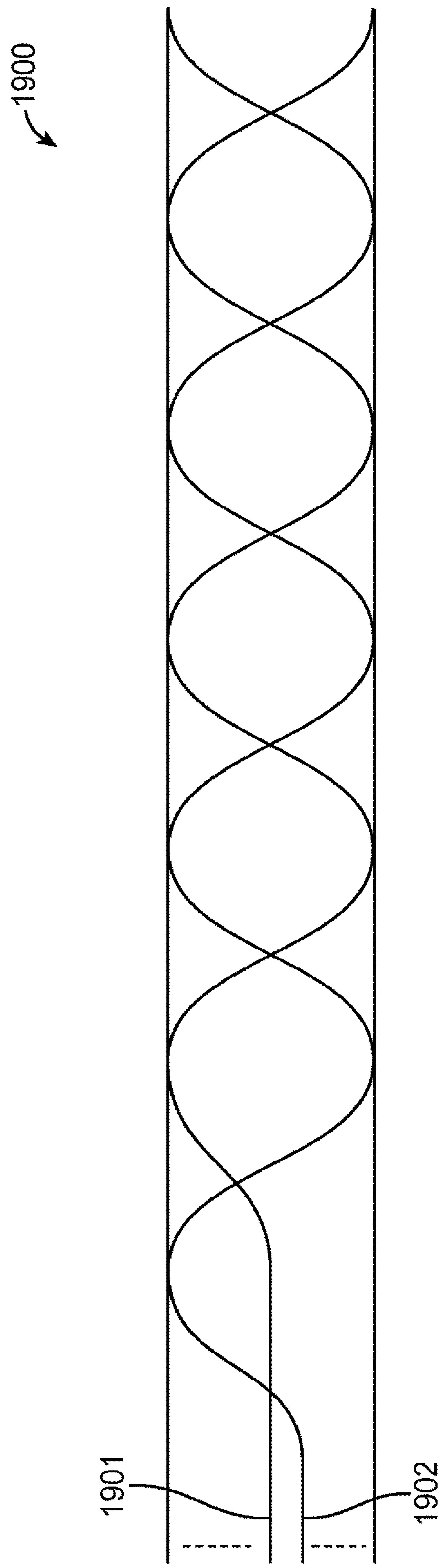


FIG. 19

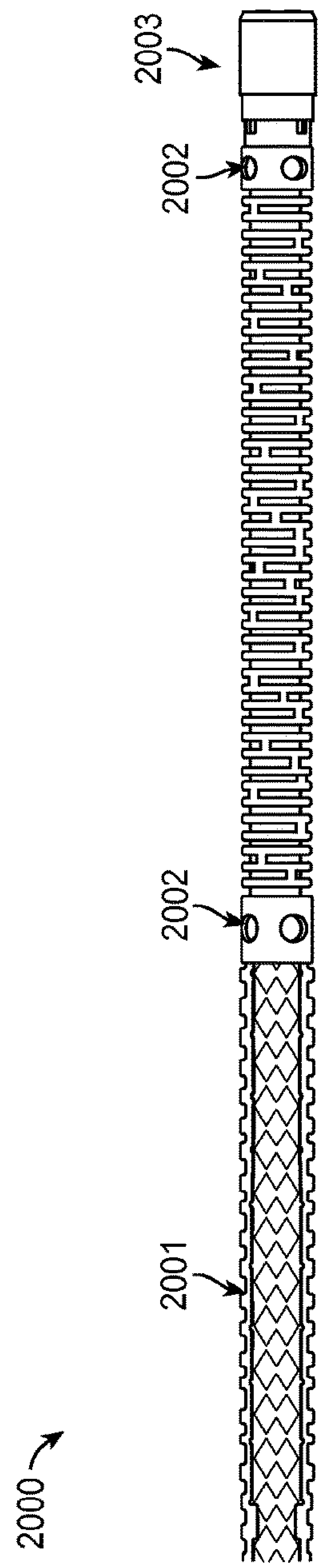


FIG. 20A

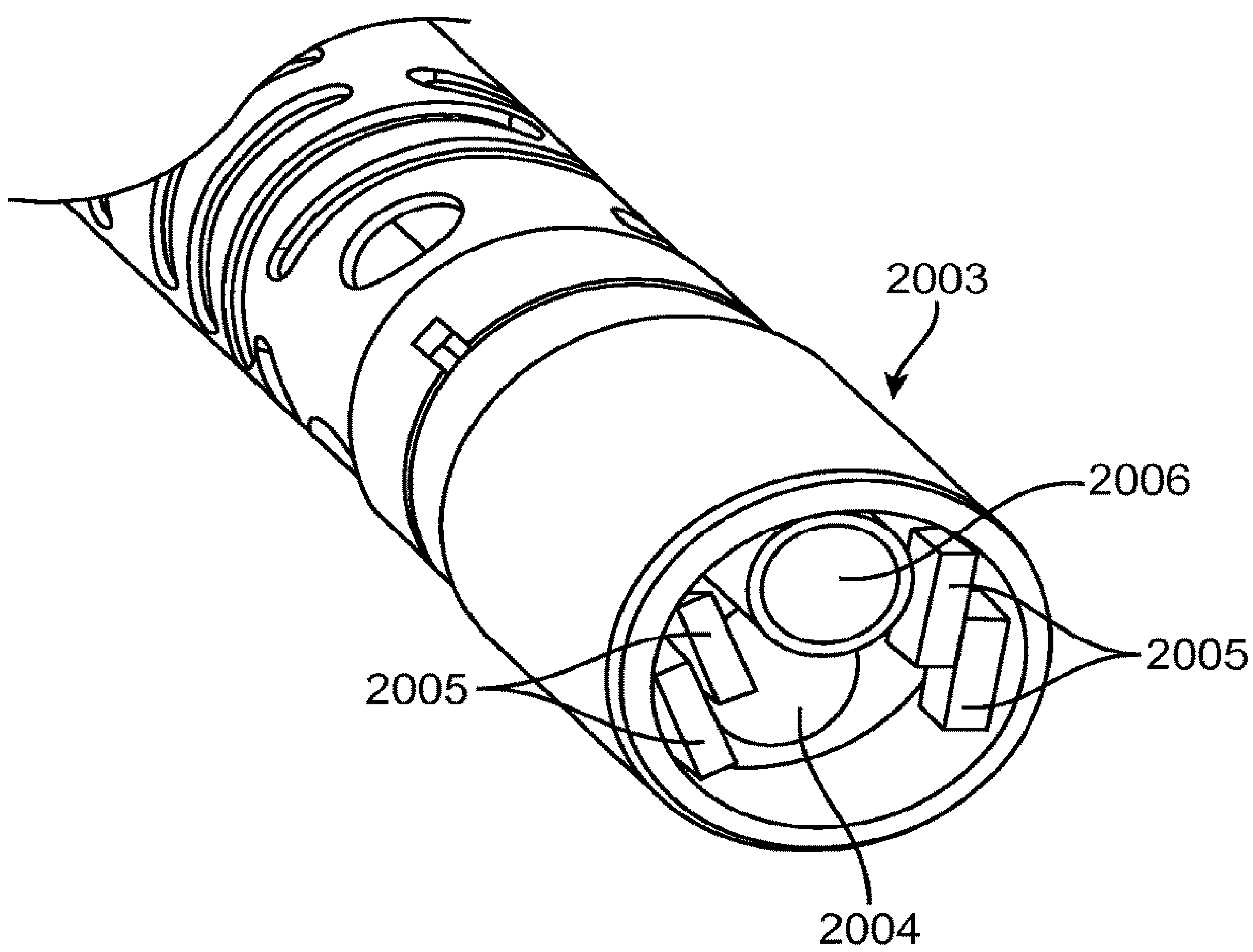


FIG. 20B

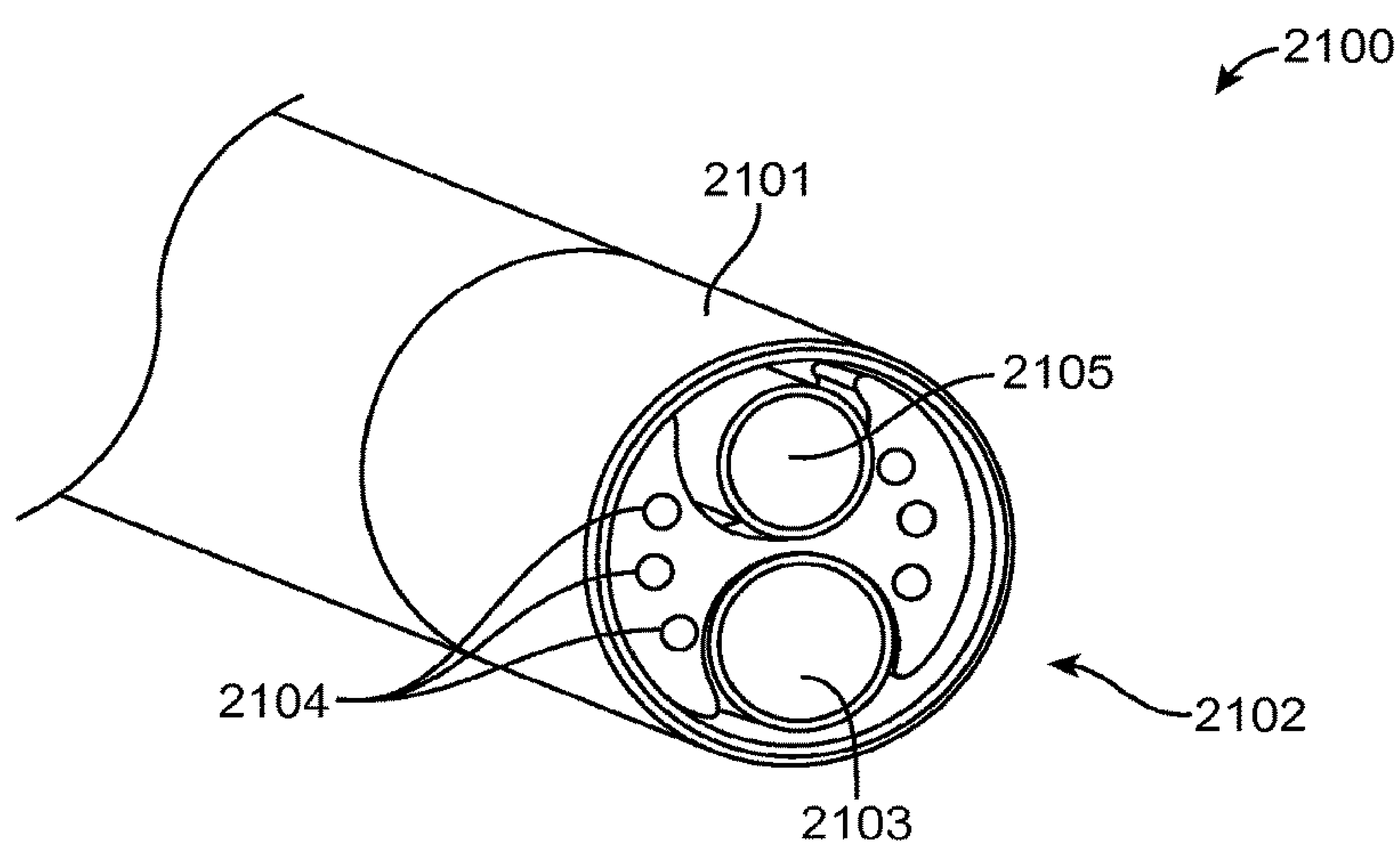
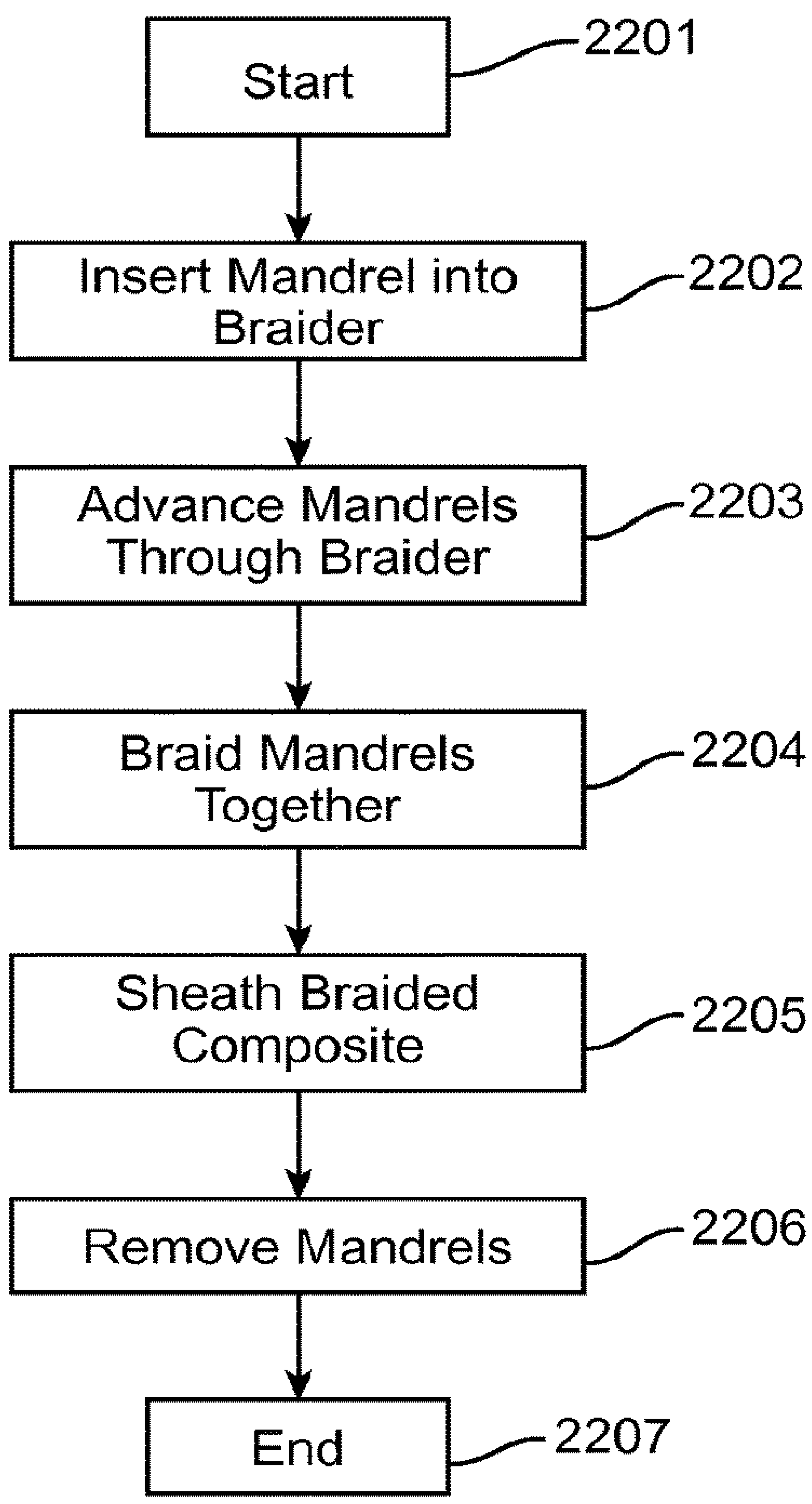


FIG. 21



Start
2201
Insert Mandrel into Braider
2202
Advance Mandrels Through Braider
2203
Braid Mandrels Together
2204
Sheath Braided Composite
2205
Remove Mandrels
2206
End
2207

FIG. 22

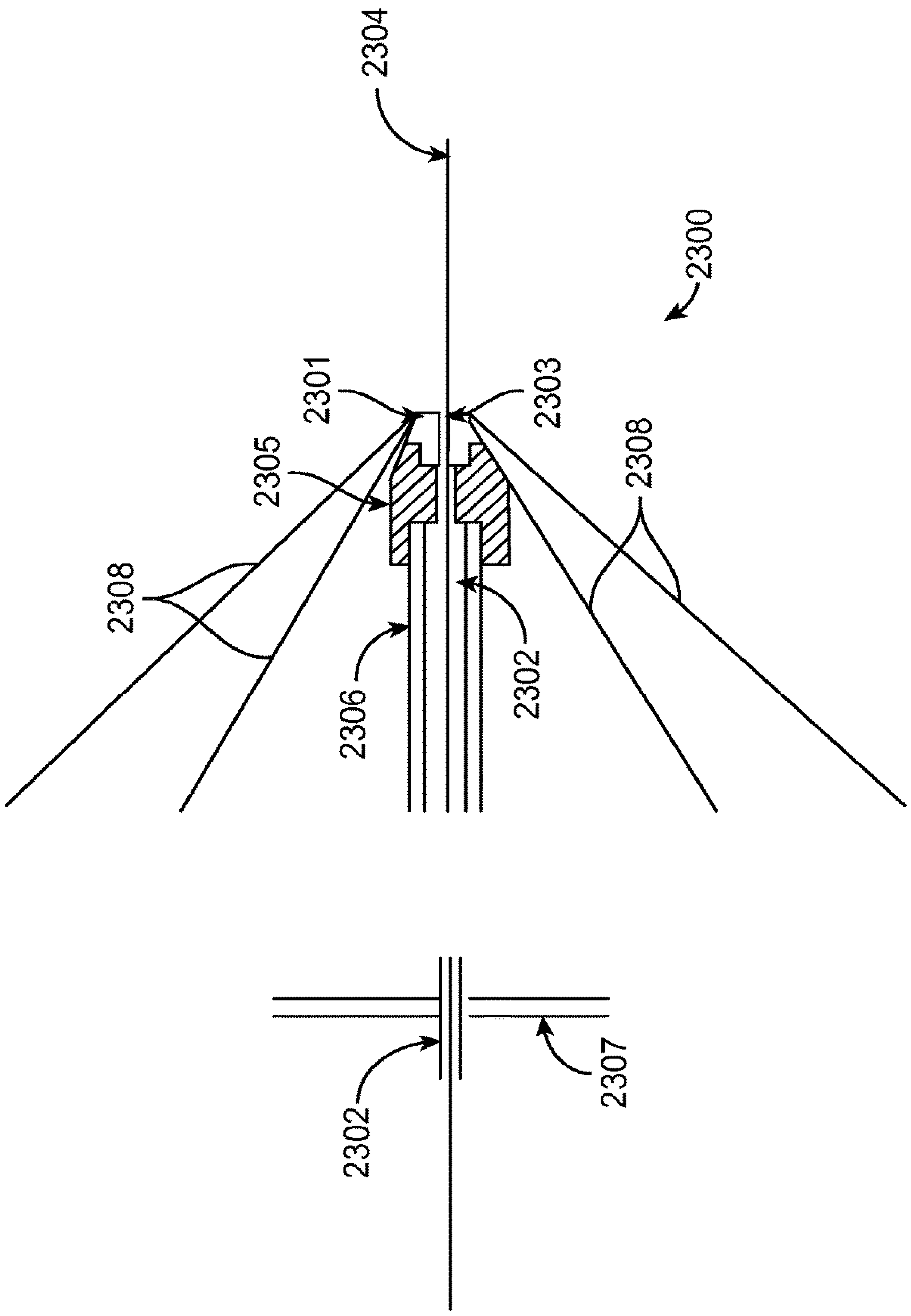


FIG. 23

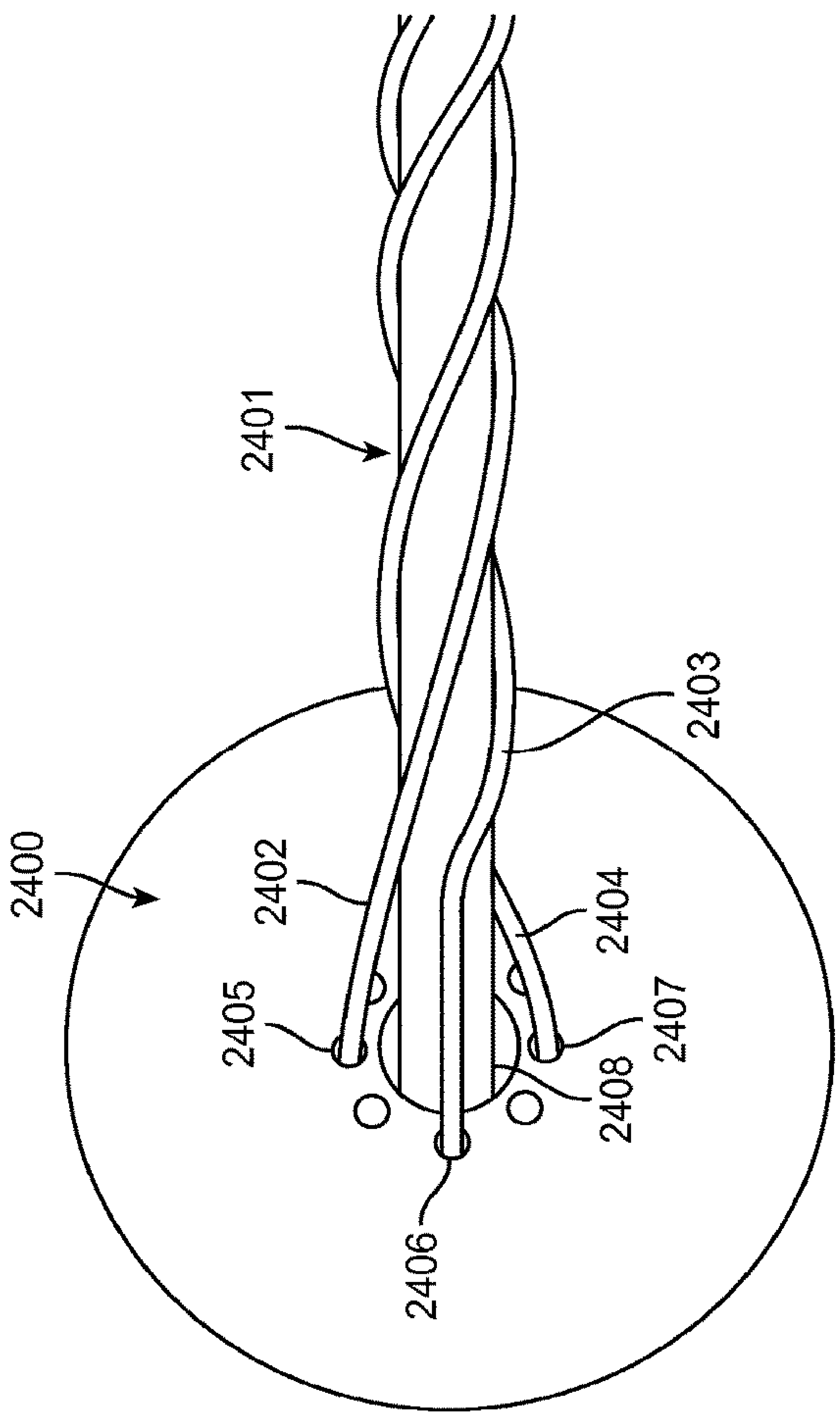
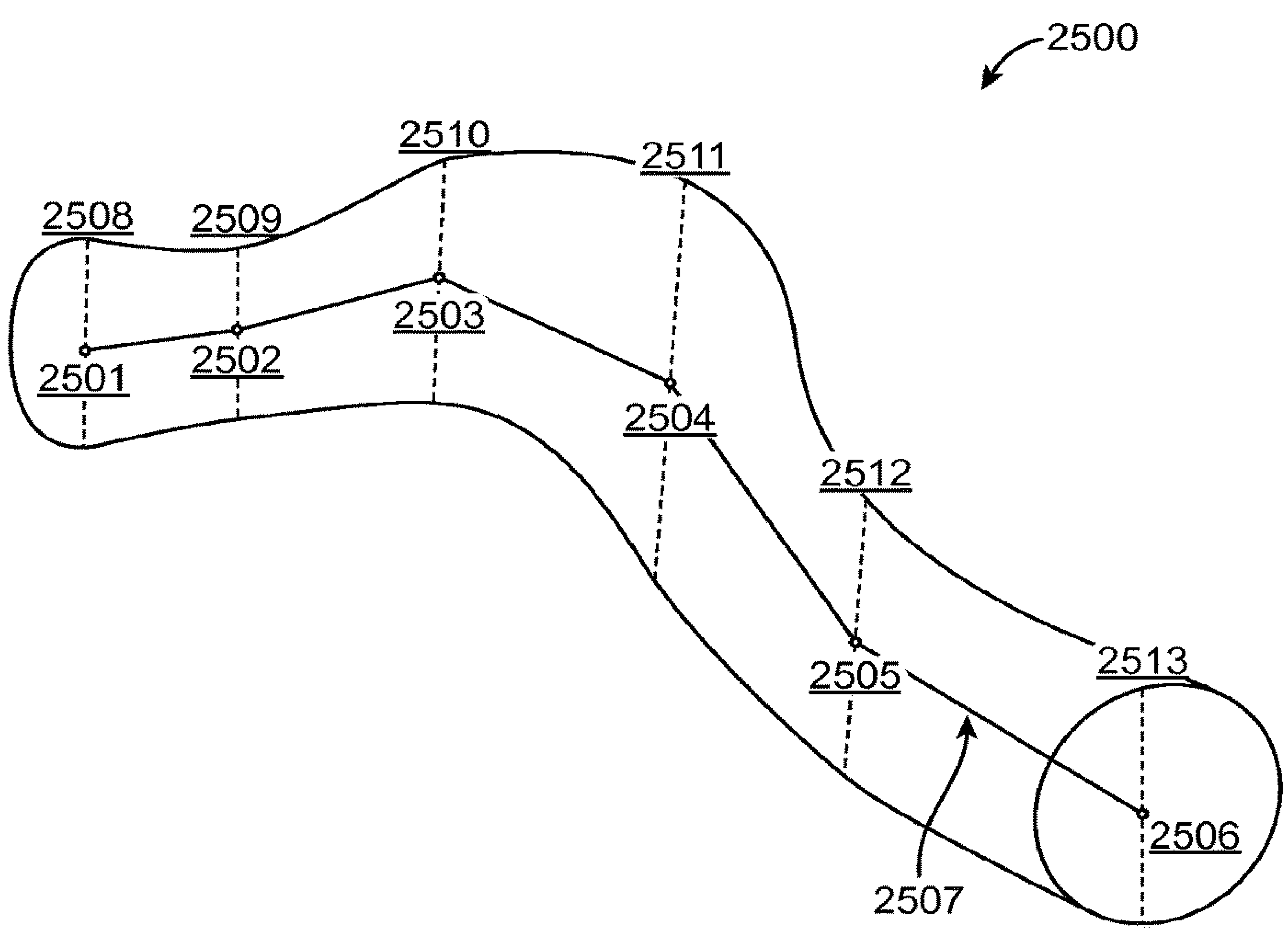


FIG. 24


2500
2508
2509
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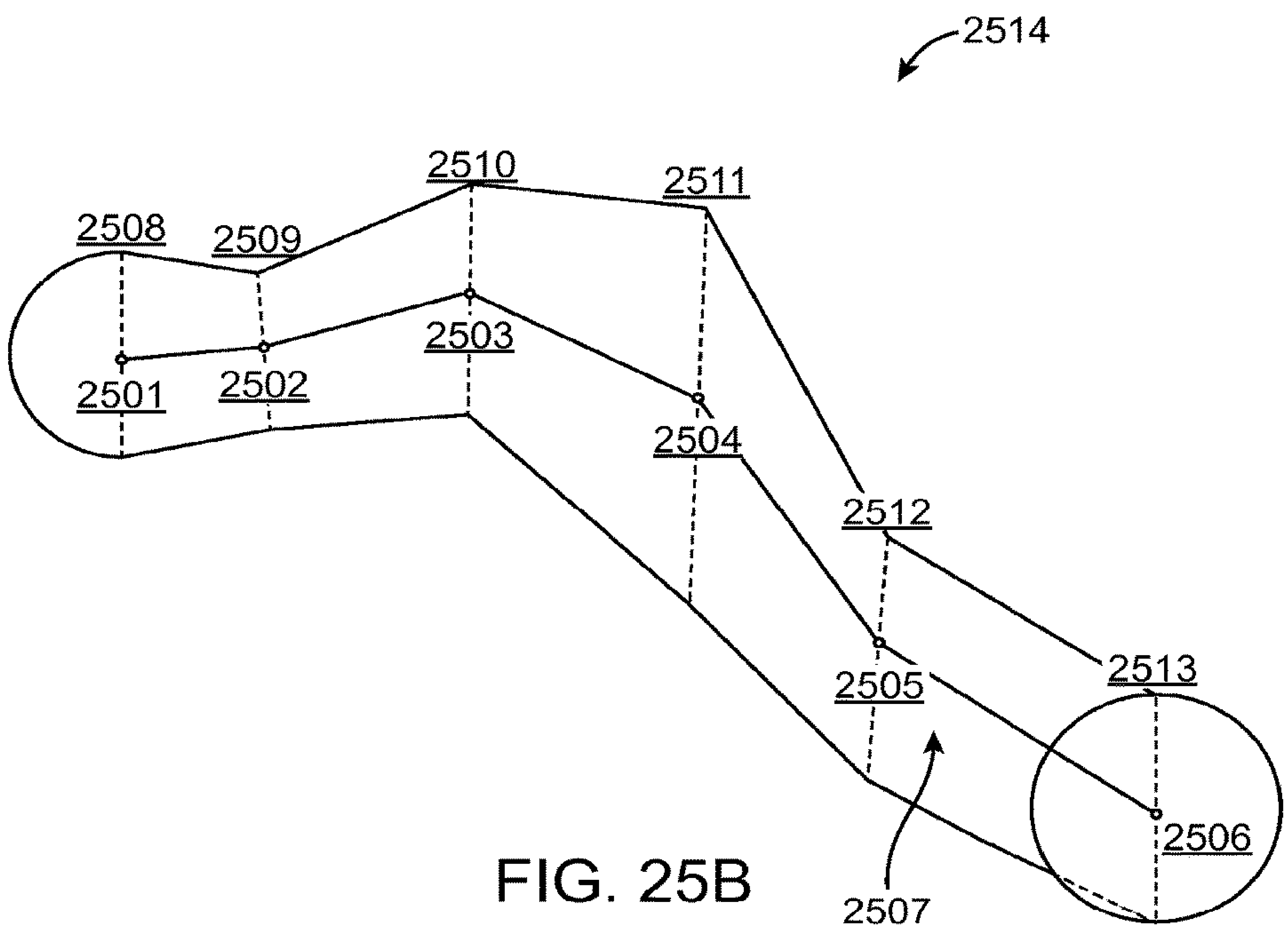
2506
2507

FIG. 25A


2514
2508
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2506
2507

FIG. 25B

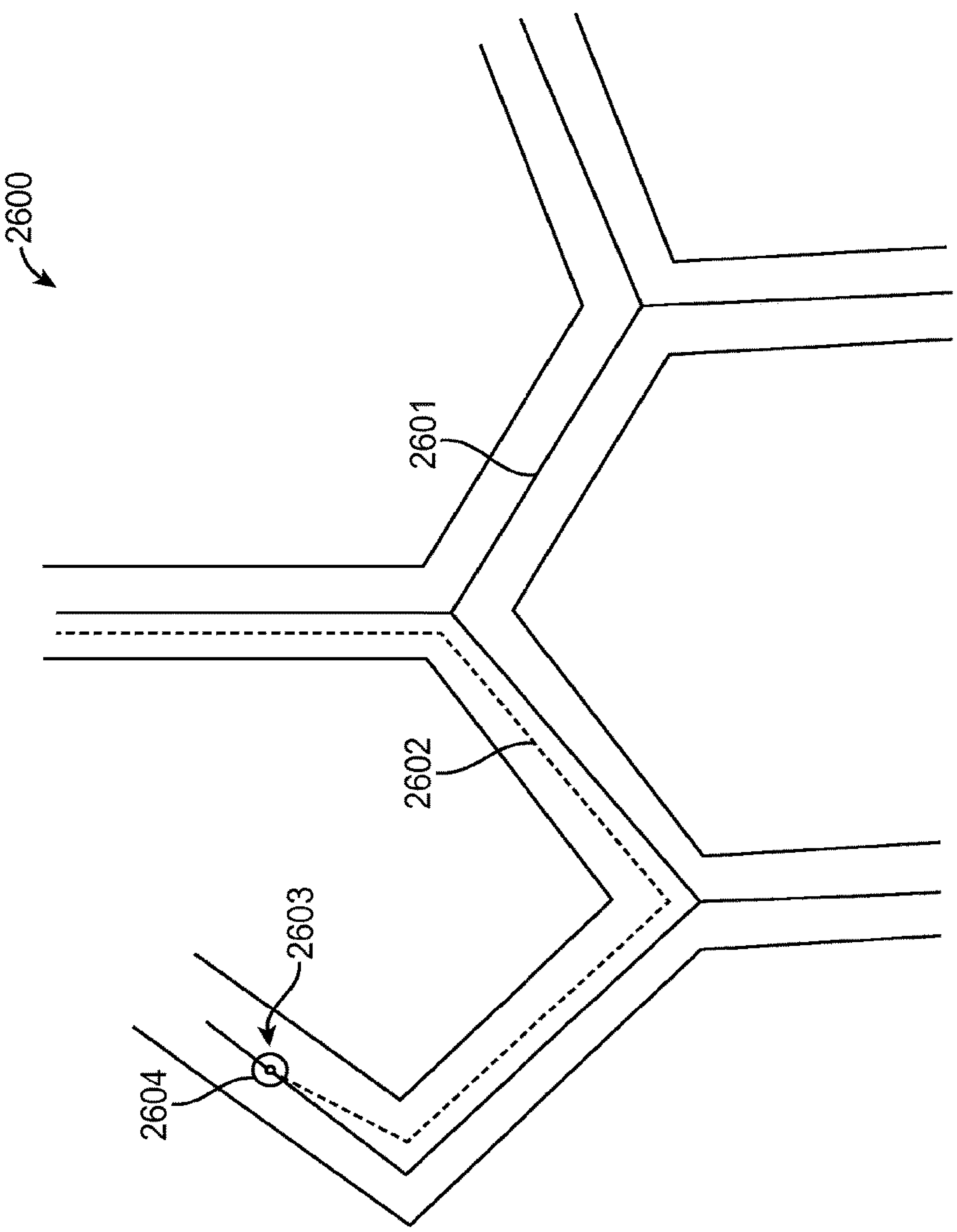

FIG. 26

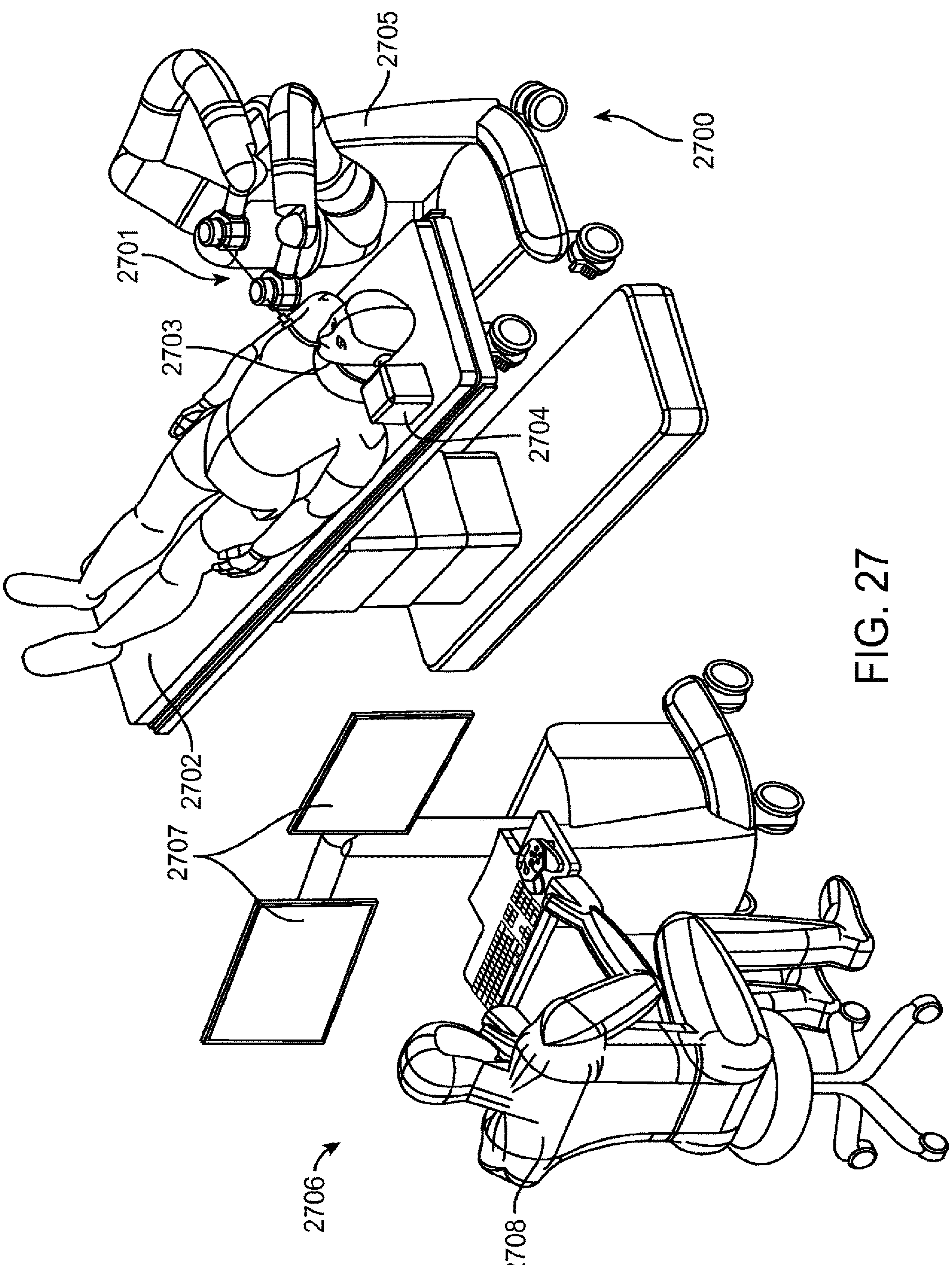

FIG. 27

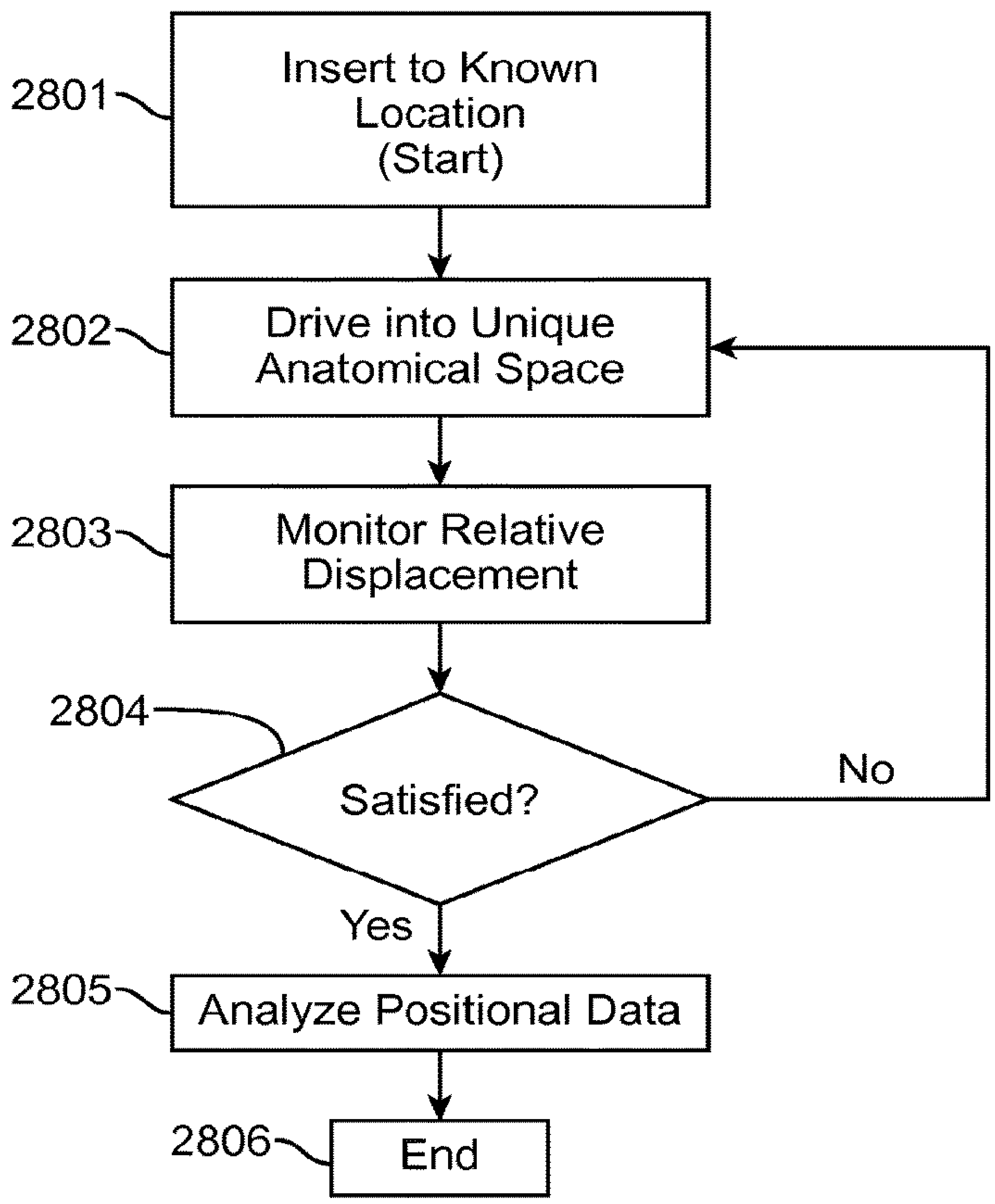
Insert to Known Location (Start)
2801
Drive into Unique Anatomical Space
2802
Monitor Relative Displacement
2803
Satisfied?
2804
No
Yes
Analyze Positional Data
2805
End
2806

FIG. 28

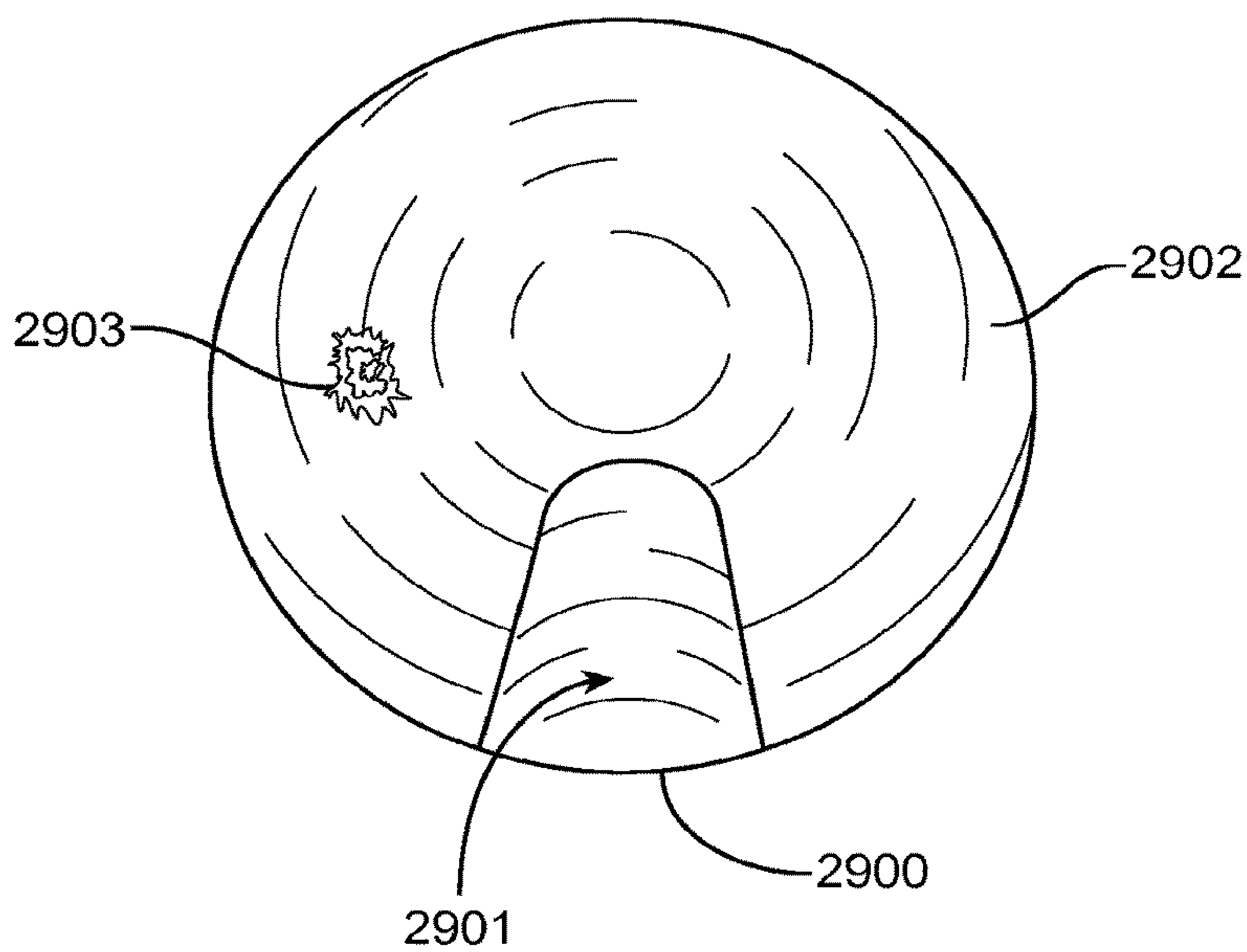

FIG. 29A

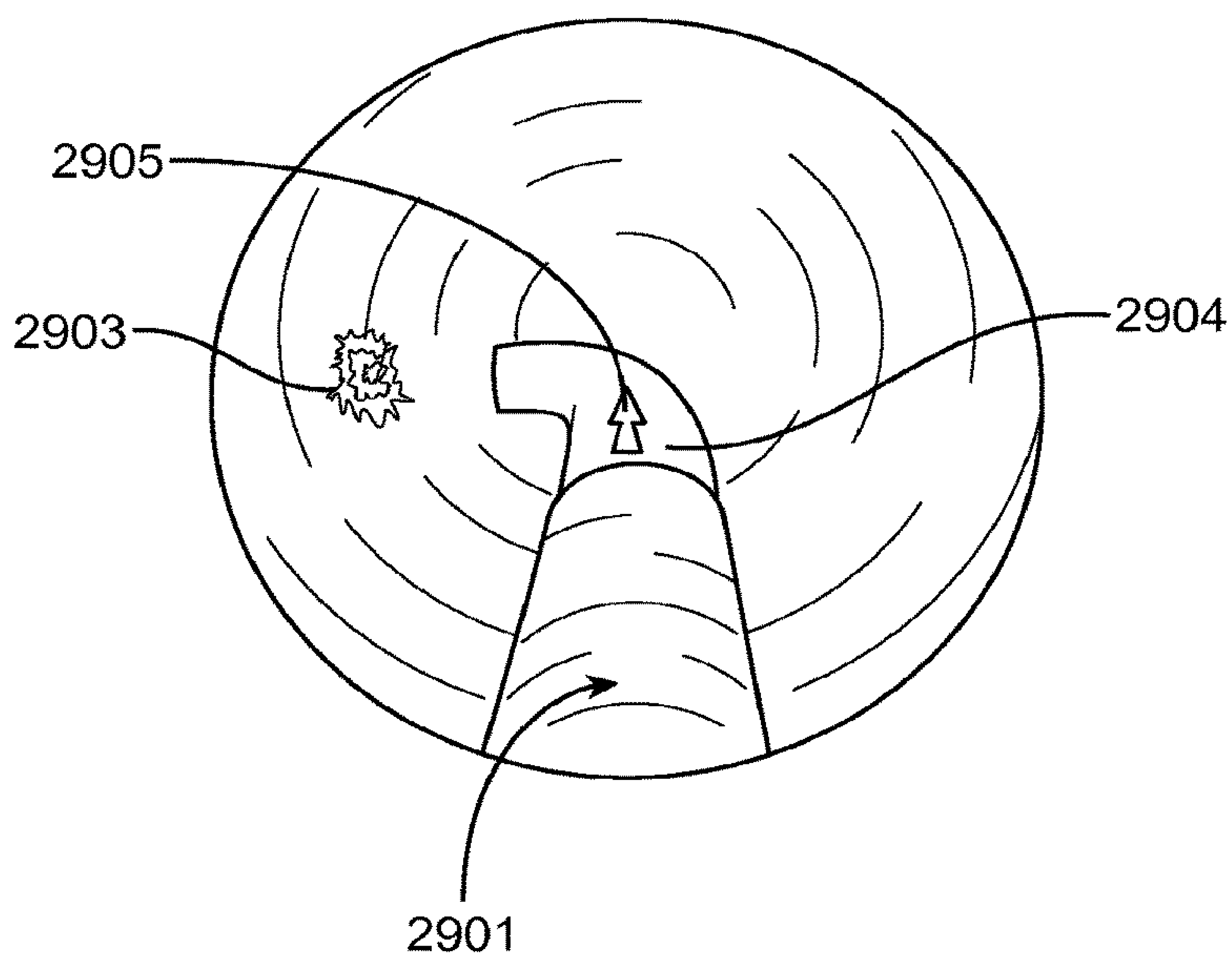

FIG. 29B

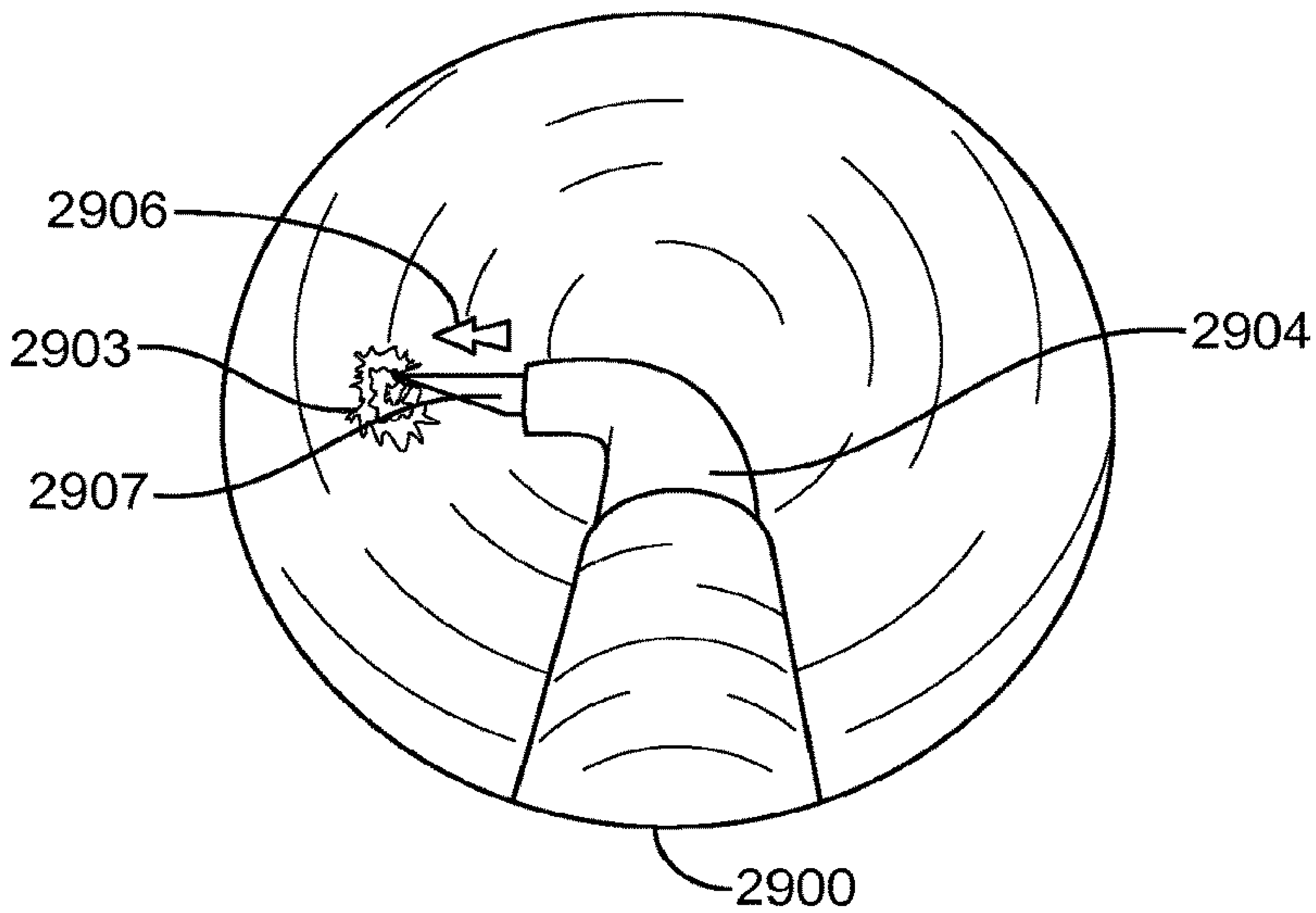

FIG. 29C

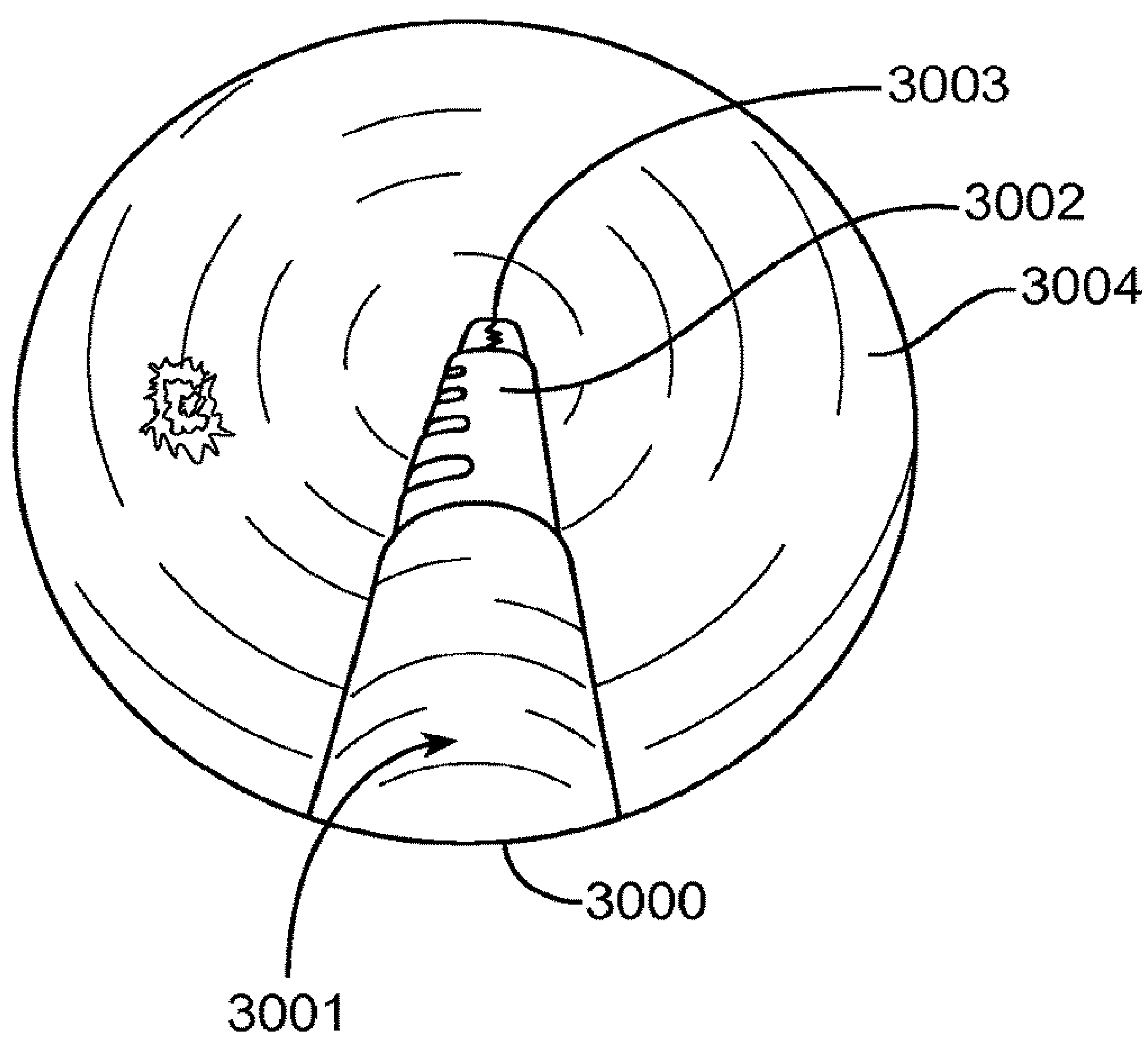

FIG. 30A

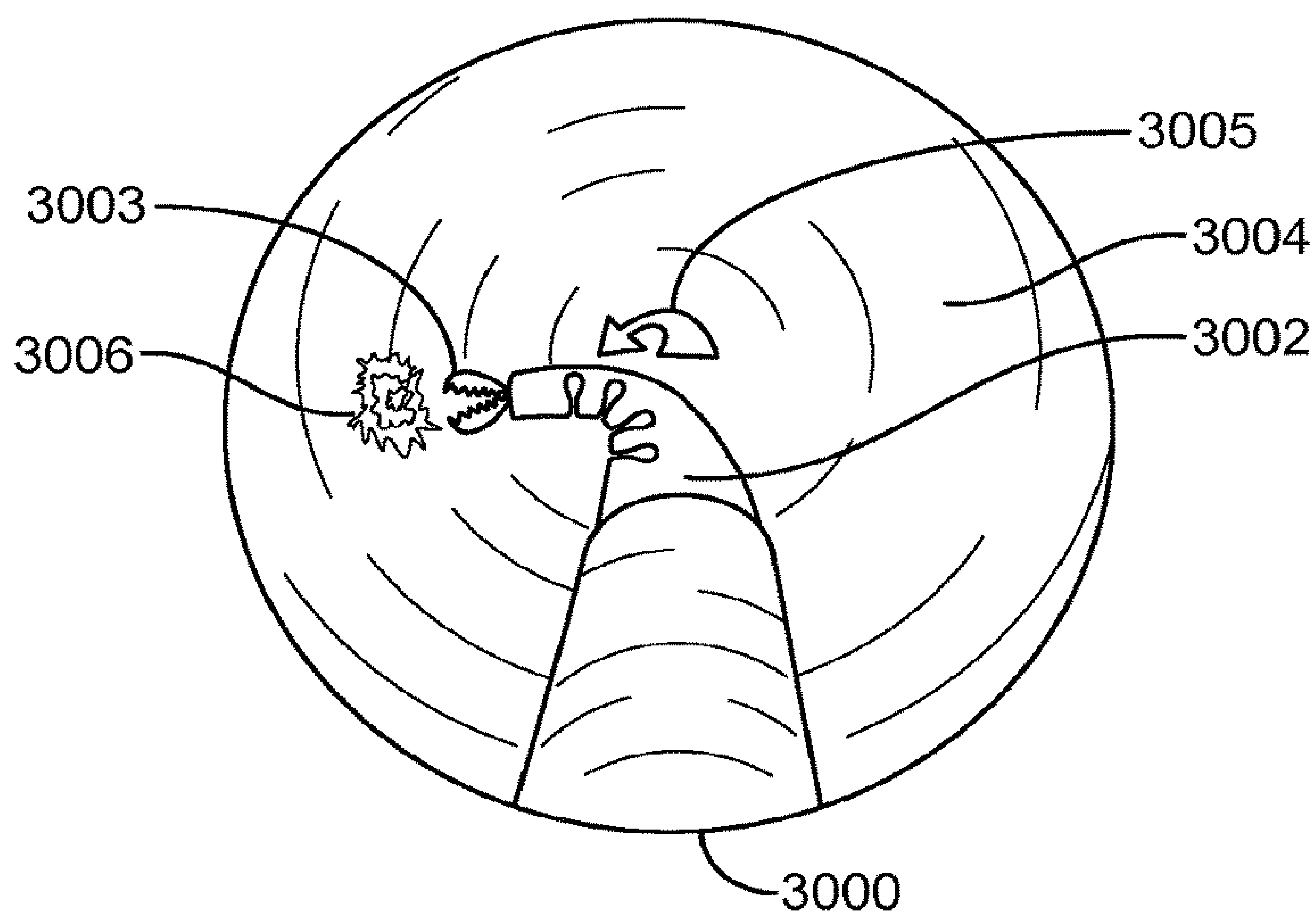

FIG. 30B

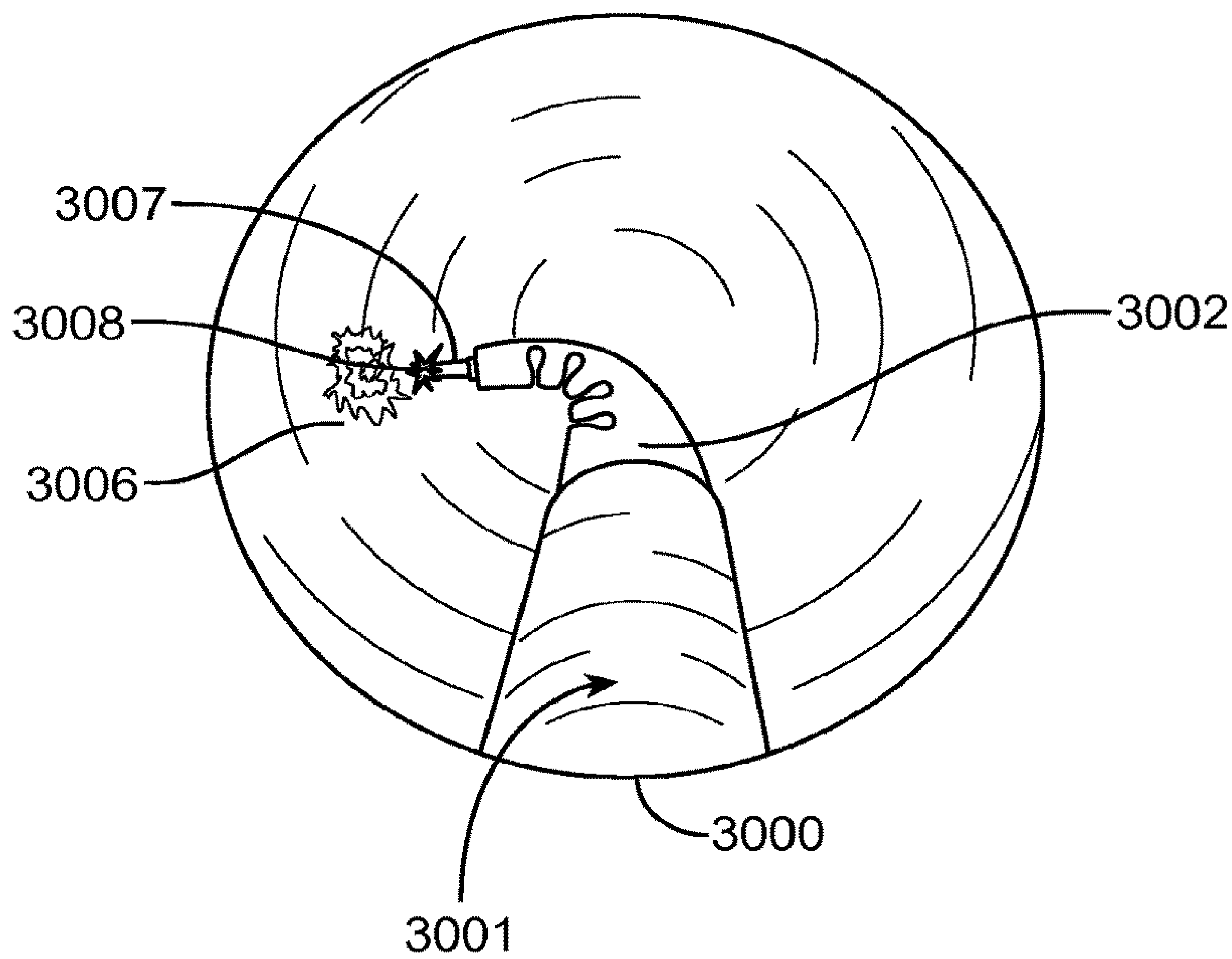

FIG. 30C

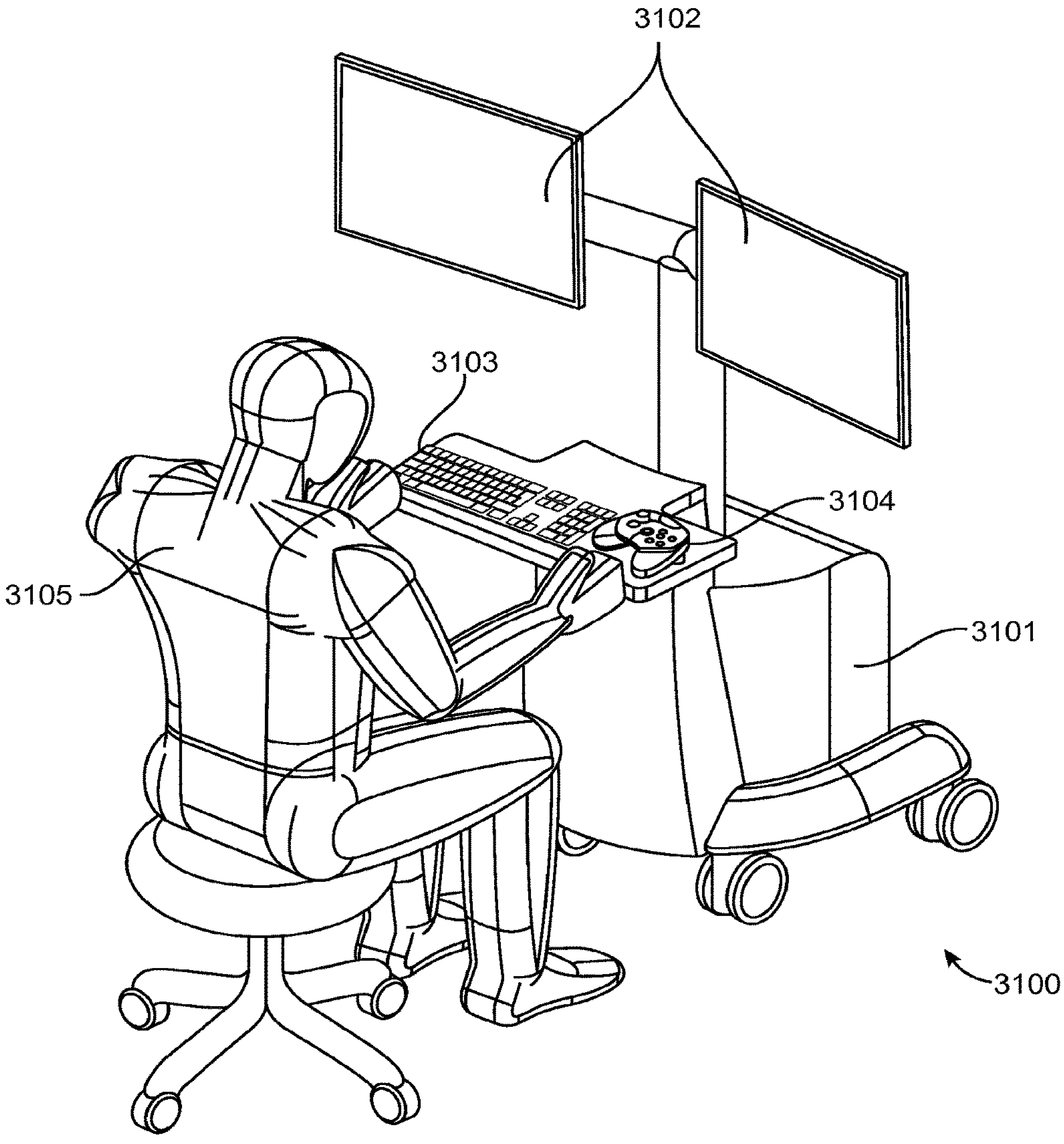

FIG. 31

INSTRUMENT DEVICE MANIPULATOR WITH TENSION SENSING APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/523,760, filed Oct. 24, 2014, which claims priority to U.S. Provisional Patent Application No. 61/895,312, filed Oct. 24, 2013; U.S. Provisional Patent Application No. 61/895,315, filed Oct. 24, 2013; U.S. Provisional Patent Application No. 61/895,602, filed Oct. 25, 2013; U.S. Provisional Patent Application No. 61/940,180, filed Feb. 14, 2014; U.S. Provisional Patent Application No. 62/019,816, filed Jul. 1, 2014; and U.S. Provisional Patent Application No. 62/037,520, filed Aug. 14, 2014; the entire contents of which are incorporated herein by reference.

This application is filed on the same day as and claims a common chain of priority as the following applications: U.S. patent application Ser. No. 14/542,373 U.S. patent application Ser. No. 14/542,387, now issued as U.S. Pat. No. 9,844,412, issued Dec. 19, 2017; and U.S. patent application Ser. No. 14/542,429.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the present application pertains to medical devices. More particularly, the field of the invention pertains to systems and tools for robotic-assisted endolumenal surgery.

2. Description of the Related Art

Endoscopy is a widely-used, minimally invasive technique for both imaging and delivering therapeutics to anatomical locations within the human body. Typically a flexible endoscope is used to deliver tools to an operative site inside the body—e.g., through small incisions or a natural orifice in the body (nasal, anal, vaginal, urinary, throat, etc.)—where a procedure is performed. Endoscopes may have imaging, lighting and steering capabilities at the distal end of a flexible shaft enabling navigation of non-linear lumens or pathways.

To assist with the navigation, the endoscopes often have a means to articulate a small distal bending section. Today's endoscopic devices are typically hand held devices with numerous levers, dials, and buttons for various functionalities, but offer limited performance in terms of articulation. For control, physicians control the position and progress of the endoscope by manipulating the leavers or dials in concert with twisting the shaft of the scope. These techniques require the physician to contort their hands and arms when using the device to deliver the scope to the desired position. The resulting arm motions and positions are awkward for physicians; maintaining those positions can also be physically taxing. Thus, manual actuation of bending sections is often constrained by low actuation force and poor ergonomics.

There are additional challenges with today's endoscopic devices. Today's endoscopes typically require support personnel to both deliver, operate and remove operative, diagnostic or therapeutic devices from the scope while the physician maintains the desired position. Today's endoscopes utilize pull wires that create issues with curve alignment and muscling. Some procedures require fluoroscopy or segmented CT scans to assist in navigating to the desired location, particularly for small lumen navigation.

Therefore, it would be beneficial to have a system and tools for endolumenal procedures that provide improved ergonomics, usability, and navigation.

SUMMARY OF THE INVENTION

In one aspect, the present invention provides for a system performing robotically-assisted surgical procedures that comprises a first robotic arm with a proximal end and a distal section, a first mechanism changer interface coupled to the distal section of the first robotic arm, a first instrument device manipulator coupled to the first mechanism changer interface, the first instrument device manipulator being configured to operate robotically-driven tools that are configured to perform surgical procedures at an operative site in a patient, and wherein the first instrument device manipulator comprises a drive unit.

In related devices, the drive unit comprises a motor. In some embodiments, the first instrument device manipulator is configured to be releasably disengaged from the mechanism changer interface and the first robotic arm.

In related devices, the first mechanism changer interface is configured to interface with a plurality of instrument device manipulators. In some embodiments, first mechanism changer interface is configured to convey electrical signals from the first robotic arm to the first instrument device manipulator.

In related devices, the present invention further comprises an endoscopic tool coupled to the first instrument device manipulator, the endoscopic tool comprising a primary elongated body. In some embodiments, an electromagnetic tracker is coupled to the distal section of the primary elongated body. In some embodiments, an accelerometer is coupled to the distal section of the primary elongated body.

In related devices, the primary elongated body comprises a working channel longitudinally aligned with a neutral axis of the primary elongated body, and a pull lumen aligned at an angle in a helix around the working channel. In some embodiments, the angle of the helix varies along the length of the primary elongated body. In some embodiments, the pull lumen contains an elongated tendon fixedly coupled to the distal section of the primary elongated body and responsive to the first instrument device manipulator.

In related devices, the endoscopic tool further comprises a secondary elongated body that is longitudinally aligned around the primary elongated body, wherein the primary elongated body comprises a proximal section and a distal section, and wherein a digital camera is coupled to the distal end. In some embodiments, the system further comprises a second robotic arm coupled to a second instrument device manipulator through a second mechanism changer interface, wherein the second instrument device manipulator is coupled to the endoscopic tool, and the first instrument device manipulator and the second instrument device manipulator are configured to align to form a virtual rail to operate the endoscopic tool. In some embodiments, the first instrument device manipulator operatively controls the secondary elongated body and the second instrument device manipulator operatively controls the primary elongated body. In some embodiments, the first robotic arm and the second robotic arm are coupled to a movable system cart. In some embodiments, the first robotic arm and the second robotic arm are coupled to an operating bed that is configured to hold the patient. In some embodiments, the system cart is configured to send sensor data to a command console and receive command signals from the command console. In some embodiments, the command console is separate from the system cart. In some embodiments, the command console comprises a display module and a control module for controlling the endoscopic tool. In some embodiments, the control module is a joystick controller.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described, by way of example, and with reference to the accompanying diagrammatic drawings, in which:

FIG. **1** illustrates a robotic endoscopic system, in accordance with an embodiment of the present invention;

FIG. **2**A illustrates a robotic surgery system in accordance with an embodiment of the present invention;

FIG. **2**B illustrates an overhead view of system **200** where anesthesia cart **201** is provided towards the head of the patient;

FIG. **2**C shows an a view of system **200** in FIG. **2**A;

FIGS. **2**D and **2**E illustrate alternative arrangements of arms **202** and **204** showing the versatility of the robotic surgical system in accordance with embodiments of the present invention;

FIG. **3**A illustrates an overhead view of a system with multiple virtual rails, in accordance with an embodiment of the present invention;

FIG. **3**B illustrates the use of robotic surgery system from FIG. **3**A with an additional robotic arm, associated tool base, and tool;

FIG. **4** illustrates a robotic surgery system with interchangeable IDMs and tools, in accordance with an embodiment of the present invention;

FIG. **5**A illustrates an implementation of a mechanism changer interface coupled to a robotic arm in a robotic system, in accordance with an embodiment of the present invention;

FIG. **5**B illustrates an alternative view of male mechanism changer interface **502** from FIG. **5**A;

FIG. **5**C illustrates a reciprocal female mechanism changer interface coupled to an instrument device manipulator for connecting with male mechanism changer interface **502** from FIGS. **5**A and **5**B;

FIG. **5**D illustrates an alternative view of female mechanism changer interface **508** from FIG. **5**C;

FIG. **6** illustrates a robotic surgery system that uses a single port laparoscopic instrument connected through an instrument interface on a single robotic arm that is directed at the abdomen of a patient, in accordance with an embodiment of the present invention;

FIG. **7** illustrates a robotic surgery system with two sets of robotic subsystems, each with a pair of arms, in accordance with an embodiment of the present invention;

FIG. **8**A illustrates a robotic surgery system with a subsystem with a single robotic arm, where a microscope tool is connected to the robotic arm through an instrument interface, in accordance with an embodiment of the present invention;

FIG. **8**B illustrates a robotic surgery system where subsystem **801** from FIG. **8**A may be used in conjunction with another subsystem to perform microsurgery, in accordance with an embodiment of the present invention;

FIG. **9**A illustrates a portion of a robotic medical system that includes a manipulator, in accordance with an embodiment of the present invention;

FIG. **9**B illustrates an alternative view of the robotic medical system disclosed in FIG. **9**A;

FIG. **10** illustrates an alternative view of the independent drive mechanism from FIGS. **9**A, **9**B with a tension sensing apparatus in accordance with an embodiment of the present invention;

FIG. **11**A illustrates a cutaway view of the independent drive mechanism from FIGS. **9**A, **9**B, and **10** from an alternate angle;

FIG. **11**B illustrates a cutaway view of the previously discussed independent drive mechanism in combination with an endoscopic tool, in accordance with an embodiment of the present invention;

FIG. **12** illustrates an alternative view of the previously-discussed independent drive mechanism with pull wires from an endoscopic tool in accordance with an embodiment of the present invention;

FIG. **13** illustrates a conceptual diagram that shows how horizontal forces may be measured by a strain gauge oriented perpendicular to the forces, in accordance with an embodiment of the invention;

FIG. **14** is an illustration of an endoscopic tool that may be used in conjunction with a robotic system **100** from FIG. **1**, in accordance with an embodiment of the present invention;

FIGS. **15**A, **15**B, **15**C, **16**A, and **16**B generally illustrate aspects of a robotically-driven endoscopic tool, in accordance with an embodiment of the present invention;

FIGS. **17**A to **17**D illustrates how prior art flexible instruments exhibit undesirable "muscling" phenomenon when tendons are pulled;

FIGS. **17**E to **17**H illustrate how prior art flexible instruments suffer from curve alignment phenomenon during use in non-linear pathways;

FIGS. **17**I and **17**J illustrate how the muscling and curve alignment phenomena is substantially resolved through the provision of a helixed section, in accordance with an embodiment of the present invention;

FIG. **18** illustrates the structure of a flexible endoscopic tool with an axially stiff tube within a lumen, in accordance with an embodiment of the present invention;

FIG. **19** illustrates the structure of a helical pattern within a lumen of a flexible endoscopic tool, in accordance with an embodiment of the present invention;

FIG. **20**A illustrates an endoscopic tool from a robotic endolumenal system, in accordance with an embodiment of the present invention;

FIG. **20**B illustrates an alternative view of endoscopic tool **2000** from FIG. **20**A;

FIG. **21** illustrates the distal end of an endoscopic tool, in accordance with an embodiment of the present invention;

FIG. **22** illustrates a flowchart for a method of constructing an endoscopic device with helical lumens, in accordance with an embodiment of the present invention;

FIG. **23** illustrates a system for manufacturing a flexible endoscope, in accordance with an embodiment of the present invention;

FIG. **24** illustrates a specialized nose cone for manufacturing an endoscopic device with helical pull lumens, in accordance with an embodiment of the present invention;

FIGS. **25**A and **25**B illustrates the relationship between centerline coordinates, diameter measurements and anatomical spaces;

FIG. **26** illustrates a computer-generated three-dimensional model representing an anatomical space, in accordance with an embodiment of the invention;

FIG. **27** illustrates a robotic endolumenal system that makes use of an electromagnetic tracker in combination with an electromagnetic field generator, in accordance with an embodiment in the present invention;

FIG. **28** illustrates a flow diagram for the steps for registration, in accordance with an embodiment of the present invention;

FIG. **29**A illustrates the distal end of an endoscopic tool within an anatomical lumen, in accordance with an embodiment of the present invention;

FIG. **29**B illustrates the endoscopic tool from FIG. **29**A in use at an operative site within an anatomical lumen, in accordance with an embodiment of the present invention;

FIG. **29**C illustrates the endoscopic tool from FIG. **29**B in use at an operative site within an anatomical lumen, in accordance with an embodiment of the present invention;

FIG. **30**A illustrates an endoscopic tool coupled to a distal flexure section within an anatomical lumen, in accordance with an embodiment of the present invention;

FIG. **30**B illustrates an endoscopic tool from FIG. **30**A with a forceps tool in use at an operative site within an anatomical lumen, in accordance with an embodiment of the present invention;

FIG. **30**C illustrates an endoscopic tool from FIG. **30**A with a laser device in use at an operative site within an anatomical lumen, in accordance with an embodiment of the present invention; and

FIG. **31** illustrates a command console for a robotic endolumenal system, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Although certain preferred embodiments and examples are disclosed below, inventive subject matter extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses, and to modifications and equivalents thereof. Thus, the scope of the claims appended hereto is not limited by any of the particular embodiments described below. For example, in any method or process disclosed herein, the acts or operations of the method or process may be performed in any suitable sequence and are not necessarily limited to any particular disclosed sequence. Various operations may be described as multiple discrete operations in turn, in a manner that may be helpful in understanding certain embodiments; however, the order of description should not be construed to imply that these operations are order dependent. Additionally, the structures, systems, and/or devices described herein may be embodied as integrated components or as separate components.

For purposes of comparing various embodiments, certain aspects and advantages of these embodiments are described. Not necessarily all such aspects or advantages are achieved by any particular embodiment. Thus, for example, various embodiments may be carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other aspects or advantages as may also be taught or suggested herein.

1. Overview.

An endolumenal surgical robotic system provides the surgeon with the ability to sit down in an ergonomic position and control a robotic endoscopic tool to the desired anatomical location within a patient without the need for awkward arm motions and positions.

The robotic endoscopic tool has the ability to navigate lumens within the human body with ease by providing multiple degrees of freedom at least two points along its length. The tool's control points provide the surgeon with significantly more instinctive control of the device as it navigates a tortuous path within the human body. The tip of the tool is also capable of articulation from zero to ninety degrees for all three hundred and sixty degrees of roll angles.

The surgical robotic system may incorporate both external sensor-based and internal vision-based navigation technologies in order to assist the physician with guidance to the desired anatomical location within the patient. The navigational information may be conveyed in either two-dimensional display means or three-dimensional display means.

2. System Components.

FIG. **1** is a robotic endoscopic system, in accordance with an embodiment of the present invention. As shown in FIG. **1**, robotic system **100** may comprises a system cart **101** with at least one mechanical arm, such as arm **102**. The system cart **101** may be in communication with a remotely-located command console (not shown). In practice, the system cart **101** may be arranged to provide access to a patient, while a physician may control the system **100** from the comfort of the command console. In some embodiments, the system cart **100** may be integrated into the operating table or bed for stability and access to the patient.

Within system **100**, arm **102** may be fixedly coupled to a system cart **101** that contains a variety of support systems, including control electronics, power sources and optical sources in some embodiments. The arm **102** may be formed from a plurality of linkages **110** and joints **111** to enable access to the patient's operative region. The system cart **103** may contain source of power **112**, pneumatic pressure **113**, and control and sensor electronics **114**—including components such as central processing unit, data bus, control circuitry, and memory—and related actuators or motors that may drive arms such as arm **102**. Power may be conveyed from the system cart **101** to the arm **102** using a variety of means known to one skilled in the art such as electrical wiring, gear heads, air chambers. The electronics **114** in system cart **101** may also process and transmit control signals communicated from a command console.

The system cart **101** may also be mobile, as shown by the wheels **115**. In some embodiments, the system cart may capable of being wheeled to the desired location near the patient. System cart(s) **101** may be located in various locations in the operating room in order to accommodate space needs and facilitate appropriate placement and motion of modules and instruments with respect to a patient. This capability enables the arms to be positioned in locations where they do not interfere with the patient, doctor, anesthesiologist or any supportive surgical equipment required for the selected procedure. During procedures, the arms with instruments will work collaboratively via user control through separate control devices, which may include a command console with haptic devices, joystick, or customized pendants.

3. Mechanical Arms.

The proximal end of arm **102** may be fixedly mounted or coupled to the cart **101**. Mechanical arm **102** comprises a plurality of linkages **110**, connected by at least one joint per arm, such as joints **111**. If mechanical arm **102** is robotic, joints **111** may comprise one or more actuators in order to affect movement in at least one degree of freedom. The arm **102**, as a whole, preferably has more than three degrees of freedom. Through a combination of wires and circuits, each arm may also convey both power and control signals from system cart **101** to the instruments located at the end of their extremities.

In some embodiments, the arms may be fixedly coupled to the operating table with the patient. In some embodiments, the arms may be coupled to the base of the operating table and reach around to access patient.

In some embodiments, the mechanical arms may not be robotically-driven. In those embodiments, the mechanical arms are comprised of linkages and set up joints that use a combination of brakes and counter-balances to hold the position of the arms in place. In some embodiments, counter-balances may be constructed from gas springs or coil springs. Brakes, such as fail safe brakes, may be mechanical or electro-mechanical. In some embodiments, the arms may be gravity-assisted passive support arms.

Distally, each arm may be coupled to a removable Instrument Device Manipulator (IDM), such as **117**, through a Mechanism Changer Interface (MCI), such as **116**. In the preferred embodiment, the MCI **116** may contain connectors to pass pneumatic pressure, electrical power, electrical signals, and optical signals from the arm to the IDM **117**. In some embodiments, MCI **116** may be as simple as a set screw or base plate connection.

IDM **117** may have a variety of means for manipulating a surgical instrument including, direct drive, harmonic drive, geared drives, belts and pulleys, or magnetic drives. One skilled in the art would appreciate that a variety of methods may be used control actuators on instrument devices.

Within the robotic system, the MCIs, such as **116**, may be interchangeable with a variety of procedure-specific IDMs, such as **117**. In this embodiment, the interchangeability of the IDMs allow robotic system **100** to perform different procedures.

Preferred embodiments may use a robotic arm with joint level torque sensing having a wrist at the distal end, such as Kuka AG's LBR5. These embodiments have a robotic arm with seven joints, with redundant joints provided to avoid potential arm collision with a patient, other robot arms, operating table, medical personal or equipment proximate to the operative field, while maintaining the wrist at the same pose so as not to interrupt an ongoing procedure. The skilled artisan will appreciate that a robotic arm with at least three degrees of freedom, and more preferably six or more degrees of freedom, will fall within the inventive concepts described herein, and further appreciate that more than one arm may be provided with additional modules, where each arm may be commonly or separately mounted on one or more carts.

4. Virtual Rail Configuration.

Arm **102** in system **100** may be arranged in a variety of postures for use in a variety of procedures. For example, in combination with another robotic system, the arm **102** of system **100** may be arranged to align its IDM to form a "virtual rail" that facilitates the insertion and manipulation of an endoscopic tool **118**. For other procedures, the arms may be arranged differently. Thus, the use of arms in system **100** provides flexibility not found in robotic systems whose design is directly tied to specific medical procedure. The arms of system **100** provides potentially much greater stroke and stowage.

FIG. **2**A illustrates a robotic surgery system **200** in accordance with an embodiment of the present invention. System **200** has first arm **202** and second arm **204** holding endoscopic tool bases **206** and **208**, respectively. Tool base **206** has controllable endoscope sheath **210** operatively connected thereto. Tool base **208** has flexible endoscope leader **212** operatively connected thereto.

Arms **202** and **204** align tool bases **206** and **208** such that proximal end **216** of sheath **210** is distal of the proximal end **222** of leader **212**, and such that leader **212** remains axially aligned with sheath **210** at an approximate angle of 180 degrees between the two arms, resulting in a "virtual rail" where the rail is approximately straight, or at 180 degrees. As will be described later, the virtual rail may have angles between 90-180 degrees. In one embodiment, sheath **210**, with leader **212** slidingly disposed therethrough, is robotically inserted through, for example, a tracheal tube (not shown) in the mouth of and into patient **211**, and ultimately into the patient's bronchial system, while continually maintaining the virtual rail during insertion and navigation. The arms may move sheath **210** and endoscope **212** axially relative to each other and in to or out of patient **211** under the control of a doctor (not shown) at a control console **203** (from FIG. **2**B).

Navigation is achieved, for example, by advancing sheath **210** along with leader **212** into the patient **211**, then leader **212** may be advanced beyond distal end **213** of the sheath, and the sheath **210** may then be brought even with the leader **212**, until a desired destination is reached. Other modes of navigation may be used, such as and not by way of limitation using a guide wire through the working channel of the leader **212**. The physician may be using any number of visual guidance modalities or combination thereof to aid navigation and performing the medical procedure, e.g., fluoroscopy, video, CT, MR etc. Distal end **220** of leader **212** may then be navigated to an operative site and tools are deployed through a longitudinally-aligned working channel within leader **212** to perform desired procedures. The virtual rail may be maintained during the navigation procedure and any subsequent operative procedures. Any number of alternative procedures that may require a tool or no tool at all can be performed using the flexible endoscope sliding through the sheath, as the skilled artisan will appreciate.

FIG. **2**B illustrates an overhead view of system **200** where anesthesia cart **201** is provided towards the head of the patient. Additionally, control console **203** with a user interface is provided to control sheath **210**, endoscope leader **212**, and the associated arms **202** and **204** and tool bases **206** and **208** (see FIG. **2**A).

FIG. **2**C shows an angled view of system **200** in FIG. **2**A. Tool modules **206** and **208** with associated sheath **210** and leader **212** are attached to arms **202** and **204** and arranged in a 180 degree virtual rail. The arms are shown on a single cart, which provides added compactness and mobility. As will be discussed later, tool bases **206** and **208** have pulley systems or other actuation systems to tension tendons in sheath **210** and leader **212** to steer their respective distal ends. Tool bases **206** and **208** may provide other desired utilities for the sheath and endoscope, such as pneumatic pressure, electrical, data communication (e.g., for vision), mechanical actuation (e.g., motor driven axels) and the like. These utilities may be provided to the tool bases through the arms, from a separate source or a combination of both.

FIGS. **2**D and **2**E illustrate alternative arrangements of arms **202** and **204** showing the versatility of the robotic surgical system in accordance with embodiments of the present invention. In FIG. **2**D, arms **202** and **204** may be extended to position the instrument (comprising sheath **210** and leader **212**) to enter the mouth of patient **211** at 75 degrees from horizontal, while still maintaining a 180 degree virtual rail. This may be done during the procedure if required to accommodate space requirements within the room. The 75 degree angle was chosen for demonstrative purposes, not by way of limitation.

FIG. **2**E shows an alternative arrangement of arms **202** and **204** where the tool bases **206** and **208** are aligned to create a virtual rail with a 90 degree angle, in accordance with an embodiment of the present invention. In this embodiment, the instrument (comprising sheath **210** and leader **212**) enters the mouth of patient **213** at 75 degrees from horizontal. Tool bases **206** and **208** are aligned such that the leader **212** bends 90 degrees at tool base **206** prior to entering the mouth of patient **213**. To facilitate the bend of leader **212**, a rigid or semi-rigid structure, such as a tube, may be used to ensure smooth extension and retraction of the leader **212** within sheath **210**. Extension and retraction of leader **212** within sheath **210** may be controlled by moving tool base **208** either closer or farther from tool base **206** along the linear path tracked by leader **212**. Extension and retraction of sheath **210** may be controlled by moving tool base **206** closer or farther from patient **213** along the linear path tracked by sheath **210**. To avoid unintended extension or retraction of leader **212** while extending or retracting sheath **210**, tool base **208** may also be moved along a linear path parallel to sheath **210**.

Virtual rails are useful in driving both rigid instrument and flexible instruments, and especially where there are telescoping requirements. The use of a virtual rail is not limited to a single rail but can consist of multiple virtual rails where the arms act in concert to maintain the individual virtual rails in performance of one or more procedures.

FIG. **3**A illustrates an overhead view of a system with multiple virtual rails, in accordance with an embodiment of the present invention. In FIG. **3**A, robot arms **302**, **304** and **306** respectively hold tool bases **308**, **310**, and **312**. Tool bases **308** and **310** may be operatively coupled to flexible tool **314** and tool **316**. Tool **314** and tool **316** may be a telerobotically-controlled flexible endoscopic instruments. Tool base **312** may be operatively coupled to a dual lumen sheath **318**, where each lumen receives tools **314** and **316**. Arms **302** and **304** may each maintain a virtual rail with robotic arm **306**, and movements of all three arms may be coordinated to maintain virtual rails and move tools **314**, **316** and sheath **318** relative to each other and the patient.

FIG. **3**B illustrates the use of the robotic surgery system from FIG. **3**A with an additional robotic arm **320** and associated tool base **322** and tool **324**. In this embodiment sheath **325** may have three lumens. Alternatively, sheath **325** may comprise more than one sheath to provide access to tools **314**, **316**, and **324**. As will be appreciated, the ability to increase or reduce the number of arms with associated modules and instruments permits a great number and flexibility of surgical configurations, which, in turn, permits re-purposing of expensive arms and use of multiple relatively-inexpensive modules to achieve great versatility at reduced expense.

Thus, to create the virtual rail, a plurality of arms and/or platforms may be utilized. Each platform/arm must be registered to the others, which can be achieved by a plurality of modalities including, vision, laser, mechanical, magnetic, or rigid attachment. In one embodiment, registration may be achieved by a multi-armed device with a single base using mechanical registration. In mechanical registration, an embodiment may register arm/platform placement, position, and orientation based on their position, orientation and placement relative to the single base. In another embodiment, registration may be achieved by a system with multiple base using individual base registration and "hand-shaking" between multiple robot arms. In embodiments with multiple bases, registration may be achieved by touching together arms from different bases, and calculating locations, orientation and placement based on (i) the physical contact and (ii) the relative locations of those bases. In some embodiments, registration targets may be used to match the position and orientations of the arms relative to each other. Through such registration, the arms and instrument driving mechanisms may be calculated in space relative to each other.

5. Mechanism Changer Interface.

Returning to FIG. **1**, robotic surgical system **100** may be configured in a manner to provide a plurality of surgical system configurations, such as by changing IDM **117** and tool **118** (also known as an end effector). The system may comprise one or more mobile robotic platforms staged at different locations in the operative room, or at a convenient nearby location. Each platform may provide some or all of power, pneumatic pressure, illumination sources, data communication cables and control electronics for a robotic arm that is coupled to the platform, and the module may draw from these utilities as well. System **100** may alternatively have multiple arms **102** mounted on one or more mobile carts **101**, or the arms may be mounted to the floor in order to provide a plurality of surgical configurations.

In addition to multiple arms and platforms, some embodiments are designed to readily exchange between multiple modules or end effector mechanisms. Various surgical procedures or steps within a procedure may require the use of different modules and the associated instrument sets, for example, exchanging between different sized sheath and endoscope combinations. Interchangeability allows the system to reconfigure for different clinical procedures or adjustments to surgical approaches.

FIG. **4** illustrates a robotic surgery system with interchangeable IDMs and tools, in accordance with an embodiment of the present invention. Surgical system **400** has a mechanical arm **401** to which IDM **402** and tool **403** are attached. Attached to system cart **404**, IDMs **405** and **406**, and associated tools **407** and **408** may be exchanged onto robotic arm **401** or picked up by a different robotic arm (not shown) to be used alone in concert with another IDM and tool. Each IDM may be a dedicated electromechanical system which may be used to drive various types of instruments and tools for specified procedures. To drive instruments, each IDM may comprise an independent drive system, which may include a motor. They may contain sensors (e.g., RFID) or memory chips that record their calibration and application related information. A system calibration check may be required after a new mechanism is connected to the robot arm. In some embodiments, an IDM may control an endoscopic sheath or flexible endoscopic leader.

In FIG. **4**, system **400** may exchange IDM **402** for IDMs **405** and **406** by itself through the use of global registration and sensors. In some embodiments, IDMs **406** and **408** are stored on system cart **404** at predetermined "docking stations" which are configured with identification and proximity sensors. Sensors at these stations may make use of technologies such as RFID, optical scanners (e.g., bar codes), EEPROMs, and physical proximity sensors to register and identify which IDMs are "docked" at the docking station. As robotic arm **401** and the IDM docking stations reside on system cart **404**, the identification and proximity sensors allow the IDMs that are resting in the docking stations to be registered relative to the robotic arm(s). Similarly, in embodiments with multiple arms on a single system cart, multiple arms may access the IDMs on the docking station using the combination of registration system and sensors discussed above.

FIG. **5** illustrates a mechanism changer interface in a robotic system, in accordance with an embodiment of the present invention. FIG. **5**A specifically illustrates an implementation of a mechanism changer interface coupled to a robotic arm in a robotic system, in accordance with an embodiment of the present invention. As shown in FIG. **5**A, the distal portion of robotic arm **500** comprises an articulating joint **501** coupled to a "male" mechanism changer interface **502**. Articulating joint **501** provides an additional degree of freedom with respect to manipulating an instrument device mechanism (not shown) that is configured to couple to robotic arm **500**. Male mechanism changer interface **502** provides a male connector interface **503** that provides a strong, physical connection to the reciprocal female receptacle connector interface on the IDM (not shown). The spherical indentations on the male connector interface **503** physically couple to reciprocal indentations on the female receptacle interface on the IDM. The spherical indentations may be extended when pneumatic pressure is conveyed along robotic arm **500** into male mechanism changer interface **502**. The male mechanism changer interface **502** also provides connections **504** for transferring for pneumatic pressure to the IDM. Additionally, this embodiment of the mechanism changer interface provides for alignment sensors **505** that ensure that the male mechanism changer interface **502** and its reciprocal female interface are properly aligned.

FIG. **5**B illustrates an alternative view of male mechanism changer interface **502** separated from robotic arm **500**. As discussed with respect to FIG. **5**A, male mechanism changer interface **502** provides for a flange-like male connector interface **503**, pneumatic connectors **504**, and alignment sensors **505**. Additionally, an electrical interface **506** for connecting electrical signals to the reciprocal interface on the IDM (not shown).

FIG. **5**C illustrates a reciprocal female mechanism changer interface coupled to an instrument device manipulator for connecting with male mechanism changer interface **502** from FIGS. **5**A and **5**B. As shown in FIG. **5**C, instrument device manipulator **507** is coupled to a female mechanism changer interface **508** that is configured to connect to male mechanism changer interface **502** on robotic arm **500**. Female mechanism changer interface **508** provides for female receptacle interface **509** that is designed to couple to the flange-like male connector interface **503** of male mechanism changer interface **502**. The female receptacle interface **509** also provides a groove to grip the spherical indentations on the male connector interface **503**. When pneumatic pressure is applied, spherical indentations on male connector **503** are extended, and male connector **503** and receptacle interfaces **509** securely couple the IDM **507** to the robotic arm **500**. Reciprocal female mechanism changer interface **508** also provides with pneumatic connectors **510** to accept the pneumatic pressure conveyed from connectors **504**.

FIG. **5**D illustrates an alternative view of female mechanism changer interface **508** from FIG. **5**C. As discussed earlier, reciprocal mechanism changer interface **508** contains a receptacle interface **509**, pneumatic connectors **510** for interfacing with mechanism changer interface **502** on robotic arm **500**. In addition, mechanism changer interface **508** also provides for an electrical module **511** for transmitting electrical signals—power, controls, sensors—to module **506** in mechanism changer interface **502**.

FIGS. **6**, **7**, **8**A, and **8**B illustrate interchangeable modules that may be operated using system **400** from FIG. **4**. FIG. **6** illustrates an embodiment of the present invention that uses a single port laparoscopic instrument **601** connected through an instrument interface **602** on a single robotic arm **603** that is directed at the abdomen **604** of a patient **605**.

FIG. **7** illustrates an embodiment of the present invention with two sets of robotic subsystems **701** and **704**, each with a pair of arms **702**, **703** and **705**, **706** respectively. Connected through instrument interfaces at the distal end of arms **702**, **703**, **705**, **706** are laparoscopic instruments **707**, **708**, **709**, **710** respectively, all instruments working together to perform procedures in an individual patient **711**.

FIG. **8**A illustrates an embodiment of the present invention with a subsystem **801** with a single robotic arm **802**, where a microscope tool **804** connected to the robotic arm **802** through an instrument interface **803**. In some embodiments, the microscopic tool **804** may be used in conjunction with a second microscope tool **805** used by a physician **806** to aid in visualizing the operational area of a patient **807**.

FIG. **8**B illustrates an embodiment of the present invention where subsystem **801** from FIG. **8**A may be used in conjunction with subsystem **808** to perform microsurgery. Subsystem **808** provides arms **809** and **810**, each with microsurgical tools **811** and **812** connected through instrument interfaces on each respective arm. In some embodiments, the one or more arms may pick up and exchange tools at a table or other suitable holding mechanism within reach of the robotic arm, such as a docking station.

In some embodiments, the mechanism changer interface may be a simple screw to secure an associated IDM. In other embodiments, the mechanism changer interface may be a bolt plate with an electrical connector.

6. Instrument Device Manipulator (IDM).

FIG. **9**A illustrates a portion of a robotic medical system that includes a manipulator, in accordance with an embodiment of the present invention. System **900** includes a partial view of a robotic arm **901**, an articulating interface **902**, an instrument device manipulator ("IDM") **903**, and an endoscopic tool **904**. In some embodiments, the robotic arm **901** may be only a linkage in a larger robotic arm with multiple joints and linkages. The articulating interface **902** couples IDM **903** to robotic arm **901**. In addition to coupling, the articulating interface **902** may also transfer pneumatic pressure, power signals, control signals, and feedback signals to and from the arm **901** and the IDM **903**.

The IDM **903** drives and controls the endoscopic tool **904**. In some embodiments, the IDM **903** uses angular motion transmitted via output shafts in order to control the endoscopic tool **904**. As discussed later, the IDM **903** may comprise a gear head, motor, rotary encoder, power circuits, control circuits.

Endoscopic tool **904** may comprise a shaft **909** with a distal tip and proximal end. A tool base **910** for receiving the control signals and drive from IDM **903** may be coupled to the proximal end of the shaft **909**. Through the signals received by the tool base **910**, the shaft **909** of endoscopic tool **904** may be controlled, manipulated, and directed based on the angular motion transmitted via output shafts **905**, **906**, **907**, and **908** (see FIG. **9**B) to the tool base **910** of the endoscopic tool **904**.

FIG. **9**B illustrates an alternative view of the robotic medical system disclosed in FIG. **9**A. In FIG. **9**B, the endoscopic tool **904** has been removed from the IDM **903**, to reveal the output shafts **905**, **906**, **907**, and **908**. Additionally, removal of the outer skin/shell of IDM **903** reveals the components below the IDM top cover **911**.

FIG. **10** illustrates an alternative view of the independent drive mechanism from FIGS. **9**A, **9**B with a tension sensing apparatus in accordance with an embodiment of the present invention. In cutaway view **1000** of IDM **903**, parallel drive units **1001**, **1002**, **1003**, and **1004** are the structurally largest components in the IDM **903**. In some embodiments, from the proximal to the distal end, a drive unit **1001** may be comprised of a rotary encoder **1006**, a motor **1005**, and a gear head **1007**. Drive units **1002**, **1003**, and **1004** may be constructed similarly—comprising of motors, encoders, and gear heads underneath the top cover **911**. In some embodiments, the motor used in the drive unit is a brushless motor. In other embodiments, the motor may be a direct current servo motor.

Rotary encoder **1006** monitors and measures the angular speed of the driveshaft of motor **1005**. In some embodiments, rotary encoder **1006** may be a redundant rotary encoder. The structure, capabilities, and use of an appropriate redundant encoder is disclosed in U.S. Provisional Patent Application No. 62/037,520, filed Aug. 14, 2014, the entire contents of which are incorporated by reference.

The torque generated by the motor **1005** may be transmitted to gear head **1007** through a shaft coupled to the rotor of motor **1005**. In some embodiments, the gear head **1007** may be attached to the motor **1005** in order to increase torque of the motor output, at the cost of the rotational speed. The increased torque generated by gear head **1007** may be transmitted into gear head shaft **1008**. Similarly, drive units **1002**, **1003**, and **1004** transmit their respective torque out through gear head shafts **906**, **907**, and **908**.

Each individual drive unit may be coupled to a motor mount at its distal end and a strain gauge mount towards its proximal end. For example, the distal end of drive unit **1001** may be clamped to motor mount **1009** and strain gauge mount **1010**. Similarly, drive unit **1002** may be clamped to motor mount **1011**, while also both being clamped to strain gauge mount **1010**. In some embodiments, the motor mounts are constructed from aluminum to reduce weight. In some embodiments, the strain gauge mounts may be adhered to a side of the drive unit. In some embodiments, the strain gauge mounts may be constructed from aluminum to reduce weight.

Electrical strain gauges **1012** and **1013** are potted and soldered to the strain gauge mount **1010** and attached using screws to motor mounts **1009** and **1011** respectively. Similarly, a pair of strain gauges (not shown) proximal to drive units **1003** and **1004** are potted and soldered to strain gauge mount **1014** and attached to motor mounts **1015** and **1016** respectively using screws. In some embodiments, the electrical strain gauges may be held in place to their respective motor mount using side screws. For example, side screws **1019** may be inserted into motor mount **1009** to hold in place strain gauge **1012**. In some embodiments, the gauge wiring in the electrical strain gauges may be vertically arranged in order to detect any vertical strain or flex in the drive unit which may be measured as horizontal displacement by the motor mount (**1009**, **1011**) relative to the strain gauge mount (**1010**).

The strain gauge wiring may be routed to circuits on the strain gauge mounts. For example, strain gauge **1012** may be routed to circuit board **1017** which may be mounted on strain gauge mount **1010**. Similarly, strain gauge **1013** may be routed to circuit board **1018** which may be also mounted on strain gauge mount **1010**. In some embodiments, circuit boards **1017** and **1018** may process or amplify the signals from strain gauges **1012** and **1013** respectively. The close proximity of circuit boards **1017** and **1018** to strain gauges **1012** and **1013** helps to reduce the signal to noise ratio in order to obtain more accurate readings.

FIG. **11**A illustrates a cutaway view of the independent drive mechanism from FIGS. **9**A, **9**B, and **10** from an alternate angle. As shown in FIG. **11**A, a portion of outer shell/skin **1101** has been cut away to reveal the innards of IDM **903**. As discussed earlier, the drive unit **1001** comprises of motor **1005**, rotary encoder **1006**, and gear head **1007**. The drive unit **1001** may be coupled to the motor mount **1009** and passes through the top cover **911** through which the output shaft **905** may be driven at the desired angular speed and torque. The motor mount **1009** may be coupled to a vertically aligned strain gauge **1012** using side screws. In addition to coupling to motor mount **1009**, the stain gauge **1012** may be potted into the strain gauge mount **1010**. In some embodiments, the output shaft **905** includes a labyrinth seal over a gear head shaft.

FIG. **11**B illustrates a cutaway view of the previously discussed independent drive mechanism in combination with an endoscopic tool, in accordance with an embodiment of the present invention. As shown in FIG. **11**B, endoscopic tool **904**, mounted on IDM **903**, contains pulleys that are longitudinally aligned with the output shafts of the IDM **903**, such as pulley **1102** which may be concentric with output shaft **905**. Pulley **1102** may be housed inside of a precision cut chamber **1103** within tool base **910** such that the pulley **1102** may be not rigidly fixed inside chamber **1103** but rather "floats" within the space in the chamber **1103**.

The splines of the pulley **1102** are designed such that they align and lock with splines on output shaft **905**. In some embodiments, the splines are designed such that there may be only a single orientation for the endoscopic tool to be aligned with IDM **903**. While the splines ensure pulley **1102** is concentrically aligned with output shaft **905**, pulley **1102** may also incorporate use of a magnet **1104** to position and axially hold the floating pulley **1102** in alignment with output shaft **905**. Locked into alignment, rotation of the output shaft **905** and pulley **1102** tensions the pull wires within endoscopic tool **904**, resulting in articulation of shaft **909**.

FIG. **12** illustrates an alternative view of the previously-discussed independent drive mechanism with pull wires from an endoscopic tool in accordance with an embodiment of the present invention. In some embodiments, the endoscopic tool may use pull wires in order to articulate and control the shaft. In those embodiments, these pull wires **1201**, **1202**, **1203**, and **1204** may be tensioned or loosened by the output shafts **905**, **906**, **907**, and **908** respectively of the IDM **903**. Accordingly, the pull wires may be robotically controlled via the control circuitry in IDM **903**.

Just as the output shafts **905**, **906**, **907**, and **908** transfer force down pull wires **1201**, **1202**, **1203**, and **1204** through angular motion, the pull wires **1201**, **1202**, **1203**, and **1204** transfer force back to the output shafts and thus to the motor mounts and drive units. For example, tension in the pull wires directed away from the output shaft results in forces pulling the motor mounts **1009** and **1011**. This force may be measured by the strain gauges, such as **1012** and **1013**, since the strain gauges are both coupled to motor mounts **1009** and **1011** and potted in the strain gauge mount **1010**.

FIG. **13** illustrates a conceptual diagram that shows how horizontal forces may be measured by a strain gauge oriented perpendicular to the forces, in accordance with an embodiment of the invention. As shown in diagram **1300**, a force **1301** may directed away from the output shaft **1302**. As the output shaft **1302** is coupled to the motor mount **1303**, the force **1301** results in horizontal displacement of the motor mount **1303**. The strain gauge **1304**, coupled to both the motor mount **1303** and ground **1305**, may thus experience strain as the motor mount **1303** causes the strain gauge **1304** to flex (causing strain) in the direction of the force **1301**. The amount of strain may be measured as a ratio of the horizontal displacement of the tip of strain gauge **1304** to the overall horizontal width of the strain gauge **1304**.

Accordingly, the strain gauge **1304** may ultimately measure the force **1301** exerted on the output shaft **1302**.

In some embodiments, the assembly may incorporate a device to measure the orientation of instrument device manipulator **903**, such as an inclinometer or accelerometer. In combination with the strain gauges, measurements from the device may be used to calibrate readings from the strain gauges, since strain gauges may be sensitive to gravitational load effects resulting from their orientation relative to ground. For example, if instrument device manipulator **903** is oriented on its side, the weight of the drive unit may create strain on the motor mount which may be transmitted to the strain gauge, even though the strain may not result from strain on the output shafts.

In some embodiments, the output signals from the strain gauge circuit boards may be coupled to another circuit board for processing control signals. In some embodiments, power signals are routed to the drive units on another circuit board from that of processing control signals.

As discussed earlier, the motors in drive units **1001**, **1002**, **1003**, and **1004** ultimately drive output shafts, such as output shafts **905**, **906**, **907**, and **908**. In some embodiments, the output shafts may be augmented using a sterile barrier to prevent fluid ingress into the instrument device manipulator **903**. In some embodiments, the barrier may make use of a labyrinth seal (**1105** from FIG. **11**A) around the output shafts to prevent fluid ingress. In some embodiments, the distal end of the gear head shafts may be covered with output shafts in order to transmit torque to a tool. In some embodiments, the output shafts may be clad in a steel cap to reduce magnetic conductance. In some embodiments, the output shafts may be clamped to the gear head shafts to assist transfer of torque.

Instrument device mechanism **903** may also be covered in a shell or skin, such as outer shell/skin **1101**. In addition to being aesthetically pleasing, the shell provides fluid ingress protection during operation, such as during medical procedures. In some embodiments, the shell may be constructed using cast urethane for electromagnetic shielding, electromagnetic compatibility, and electrostatic discharge protection.

In an embodiment of the present invention, each of those output shafts in individually tension may pull wires in an endoscopic tool that makes use of steerable catheter technology. Tensile force in the pull wires may be transmitted to the output shafts **905**, **906**, **907** and **908** and down to a motor mount, such as motor mounts **1009** and **1011**.

7. Endoscopic Tool Design.

In a preferred embodiment, robotic system **100** from FIG. **1** may drive a tool customized for endolumenal procedures, such as endoscopic tool **118**. FIG. **14** is an illustration of an endoscopic tool that may be used in conjunction with a robotic system **100** from FIG. **1**, in accordance with an embodiment of the present invention. Endoscopic tool **1400** may be arranged around nested longitudinally-aligned tubular bodies, referred to as a "sheath" and a "leader". The sheath **1401**, the tubular tool with the larger outer diameter, may be comprised of a proximal sheath section **1402**, a distal sheath section **1403**, and a central sheath lumen (not shown). Through signals received in the sheath base **1404**, the distal sheath portion **1403** may be articulated in the operator's desired direction. Nested within the sheath **1401** may be a leader **1405** with a smaller outer diameter. The leader **1405** may comprise a proximal leader section **1406** and a distal leader section **1407**, and a central working channel. Similar to sheath base **1404**, leader base **1408** controls articulation of the distal leader section **1407** based on control signals communicated to leader base **1408**, often from the IDMs (e.g., **903** from FIG. **9**A).

Both the sheath base **1404** and leader base **1408** may have similar drive mechanisms, to which control tendons within sheath **1401** and leader **1405** are anchored. For example, manipulation of the sheath base **1404** may place tensile loads on tendons in the sheath **1401**, therein causing deflection of distal sheath section **1403** in a controlled manner. Similarly, manipulation of the leader base **1408** may place tensile loads on the tendons in leader **1405** to cause deflection of distal leader section **1407**. Both the sheath base **1404** and leader base **1408** may also contains couplings for the routing of pneumatic pressure, electrical power, electrical signals or optical signals from the IDMs to the sheath **1401** and leader **1404**.

Control tendons within the sheath **1401** and leader **1405** may be routed through the articulation section to an anchor positioned distal to the articulation section. In a preferred embodiment, the tendons within sheath **1401** and leader **1405** may consist of a stainless steel control tendon routed through a stainless steel coil, such as a coil pipe. One skilled in the arts would appreciate that other materials may be used for the tendons, such as Kevlar, Tungsten and Carbon Fiber. Placing loads on these tendons causes the distal sections of sheath **1401** and leader **1405** to deflect in a controllable manner. The inclusion of coil pipes along the length of the tendons within the sheath **1401** and leader **1405** may transfer the axial compression back to the origin of the load.

Using a plurality of tendons, the endoscopic tool **1400** has the ability to navigate lumens within the human body with ease by providing a plurality of degrees of freedom (each corresponding to an individual tendon) control at two points—distal sheath section **1403** and distal leader section **1407**—along its length. In some embodiments, up to four tendons may be used in either the sheath **1401** and/or leader **1405**, providing up to eight degrees of freedom combined. In other embodiments, up to three tendons may be used, providing up to six degrees of freedom.

In some embodiments, the sheath **1401** and leader **1405** may be rolled 360 degrees, providing for even more tool flexibility. The combination of roll angles, multiple degrees of articulation, and multiple articulation points provides the surgeon with a significant improvement to the instinctive control of the device as it navigates a tortuous path within the human body.

FIGS. **15**A, **15**B, **15**C, **16**A, and **16**B generally illustrate aspects of a robotically-driven endoscopic tool, such a sheath **210** and leader **212** from FIG. **2**, in accordance with an embodiment of the present invention. FIG. **15**A illustrates an endoscopic tool with sheath **1500** having distal end **1501** and proximal end **1502** and lumen **1503** running between the two ends. Lumen **1503** may be sized to slidingly receive a flexible endoscope (such as leader **1600** from FIG. **16**). Sheath **1500** has walls **1504** with tendons **1505** and **1506** running inside the length of walls **1504** of sheath **1500**. Tendons **1505** and **1506** may slidingly pass through conduits **1507** and **1508** in walls **1504** and terminate at distal end **1501**. In some embodiments, the tendons may be formed from steel. Appropriate tensioning of tendon **1505** may compress distal end **1501** towards conduit **1507**, while minimizing bending of the helixed section **1510**. Similarly, appropriate tensioning of tendon **1506** may compress distal end **1501** towards conduit **1508**. In some embodiments, lumen **1503** may not be concentric with sheath **1500**.

Tendons **1505** and **1506** and associated conduits **1507** and **1508** from sheath **1500** from FIG. **15**A preferably do not run straight down the entire length of sheath **1500**, but helix around sheath **1500** along helixed section **1510** and then run longitudinally straight (i.e., approximately parallel to the neutral axis) along distal section **1509**. It will be appreciated that helixed section **1510** may begin from the proximal end of distal section **1509** extending proximally down sheath **1510** and may terminate at any desired length for any desired or variable pitch. The length and pitch of helixed section **1510** may be determined based on the desired properties of sheath **1500**, taking into account desired flexibility of the shaft, and increased friction in the helixed section **1510**. Tendons **1505** and **1506** may run approximately parallel to central axis **1511** of sheath **1500** when not in the helixed section, such as the proximal and distal sections of the endoscope **1500**.

In some embodiments, the tendon conduits may be at ninety degrees to each other (e.g., 3-, 6-, 9- and 12-o'clock). In some embodiments, the tendons may be spaced one hundred and twenty degrees from each other, e.g., three total tendons. In some embodiments, the tendons may be not be equally spaced. In some embodiments, they may be to one side of the central lumen. In some embodiments, the tendon count may differ from three or four.

FIG. **15**B shows a three-dimensional illustration of an embodiment of sheath **1500** with only one tendon for the purpose of clarifying the distinction between non-helixed section **1509** and a variable pitch helixed section **1510**. While one tendon may be used, it may be preferable to use multiple tendons. FIG. **15**C shows a three-dimensional illustration of an embodiment of sheath **1500** with four tendons extending along distal section **1509**, variable pitch helixed section **1510**.

FIG. **16**A illustrates an endoscopic leader **1600** with distal end **1601** and proximal end **1602**, that may be sized to slidingly reside within the sheath **1500** from FIG. **15**. Leader **1600** may include at least one working channel **1603** passing through it. Proximal end **1502** of sheath **1500** and proximal end **1602** of leader **1600** are, respectively, operatively connected to tool bases **206** and **208** from FIG. **2** respectively. Tendons **1604** and **1605** slidingly pass through conduits **1606** and **1607** respectively in walls **1608** and terminate at distal end **1601**.

FIG. **16**B illustrates the distal end **1601** of leader **1600**, an exemplary embodiment, that has imaging **1609** (e.g., CCD or CMOS camera, terminal end of imaging fiber bundle etc.), light sources **1610** (e.g., LED, optic fiber etc.) and may include at least one working channel opening **1603**. Other channels or operating electronics **1606** may be provided along leader **1600** to provide various known capabilities at the distal end, such as wiring to camera, insufflation, suction, electricity, fiber optics, ultrasound transducer, EM sensing, and OCT sensing.

In some embodiments, the distal end **1601** of leader **1600** may include a "pocket" for insertion of a tool, such as those disclosed above. In some embodiments, the pocket may include an interface for control over the tool. In some embodiments, a cable, such as an electrical or optical cable, may be present in order communicate with the interface.

In some embodiments, both sheath **1500** from FIG. **15**A and leader **1600** from FIG. **16**A may have robotically-controlled steerable distal ends. The structure of sheath **1500** and leader **1600** enabling this control may be substantially the same. Thus, discussion for the construction of sheath **1500** will be limited to that of the sheath **1500** with the understanding that the same principles apply to the structure of the leader **1600**.

Therefore, tendons **1604** and **1605** and associated conduits **1606** and **1607** from the leader **1600** from FIG. **16**A do not run longitudinally straight (i.e., approximately parallel to the neutral axis) down the length of leader **1600**, but helix along different portions of leader **1600**. As with the helixed tendons and conduits in sheath **1500**, the helixed sections of leader **1600** may be determined based on the desired properties of the leader, taking into account desired flexibility of the shaft, and increased friction in the helixed section. Tendons **1604** and **1605** run approximately parallel to central axis of leader **1600** when not in the helixed section.

The helixed section, as described more fully below, may help isolate the bending to the distal section, while minimizing any bending that occurs along the shaft proximal to the distal section. In some embodiments of the present invention, the helix pitch of the conduits in sheath **1500** and leader **1600** may be varied along the length of the helixed section, which, as more fully described below will alter the stiffness/rigidity of the shaft.

The use of helixed conduits and helixed tendons in sheath **1500** and leader **1600** present significant advantages over previous flexible instruments without helixed conduits, particularly when navigating non-linear pathways in anatomical structures. When navigating curved pathways, it may be preferable for sheath **1500** and leader **1600** to remain flexible over most of the lengths thereof, and to have a controllably steerable distal end section, while also minimal secondary bending of the instrument proximal to the distal bending section. In previous flexible instruments, tensioning the tendons in order to articulate the distal end resulted in unwanted bending and torqueing along the entire length of the flexible instrument, which may be referred to as "muscling" and "curve alignment" respectively.

FIGS. **17**A to **17**D illustrates how prior art flexible instruments exhibit undesirable "muscling" phenomenon when tendons are pulled. In FIG. **17**A, a previous endoscope **1700** may have four tendons or control wires along the length of the endoscope **1700** that run approximately parallel to the neutral axis **1701**. Only tendons **1702** and **1703** are shown in cross section traveling through conduits **1704** and **1705** (also known as control lumens) in the shaft wall, each of which are fixedly connected to a control ring **1706** on the distal end of the endoscope **1700**. Endoscope **1700** may be intentionally designed to have a bending section **1707** and shaft **1708**. In some flexible instruments, the shaft **1708** may incorporate stiffer materials, such as stiffeners.

FIG. **17**B illustrates an idealized articulation of bending section **1707**. By pulling or exerting tension on tendon **1703**, articulation of only the distal bending section **1707** results in an amount represented by ϕ, where the length difference at the proximal ends of tendons **1702** and **1703** would be a $f(\phi)$. In contrast, the shaft **1708** would remain straight along the neutral axis **1701**. This may be achieved by having a proximal region **1708** of a significantly higher stiffness than the distal region of **1707**.

FIG. **17**C illustrates the real world result from tensioning tendon **1703**. As shown in FIG. **17**C, pulling tendon **1703** results in compressive forces along the entire length of the shaft as the tension is non-localized. In an idealized situation, were tendon **1703** along the neutral axis **1701**, the entire compressive load would transmit equally down the central axis and most or all bending would occur at the bending section **1707**. However, where the tendon **1703** runs along the periphery of the shaft **1708**, such as in endoscope **1700**, the axial load is transferred off the neutral axis **1701** in the same radial orientation of the neutral axis which creates a cumulative moment along the neutral axis. This causes the shaft **1708** to bend (depicted as **8**), where the bend in the shaft **1708** will be in the same direction as the bend in the bending section **1707**. The length along conduit **1704** and conduit **1705** must change as the endoscope **1700** and distal bend section **1707** bend. The amount tendons **1702** and **1703** extend from the proximal end is f(ϕ,θ), as tendon **1703** will need to shorten and tendon **1702** will need to lengthen. This phenomenon, where the shaft **1707** and distal bending section **1708** bend from pulling tendon **1703**, is referred to as "muscling."

FIG. **17**D illustrates the forces that contribute to muscling in three-dimensions. As shown by FIG. **17**D, tensioning tendon **1703** along endoscope **1700** causes the tendon **1703** to directionally exert forces **1712** towards one side of the instrument. The direction of forces **1712** reflect that the tension in tendon **1703** causes the tendon to seek to follow a straight line from the tip of the distal bending section **1707** to the base of the shaft **1708**, i.e., the lowest energy state as represented by the dotted line **1713**. As will be appreciated, if the shaft **1708** is rigid (i.e., not susceptible to bending under the applicable forces), only the distal bending section **1707** will bend. However, in many applications it is not desirable to make the shaft rigidity sufficiently different from the distal end to adequately minimize the muscling phenomenon.

FIGS. **17**E to **17**H illustrate how previous flexible instruments suffer from curve alignment phenomenon during use in non-linear pathways. FIG. **17**E shows a previous flexible endoscope **1700** at rest within a non-linear path, represented by having a bend τ along the shaft **1708** of endoscope **1700**. For example, this may result from the instrument navigating past a bend in the bronchial lumens. Due to the non-linear bend, tendons **1702** and **1703** in endoscope **1700** need to lengthen or shorten at the proximal end by a length to accommodate the non-linear bend, which length is represented by F(τ). Extension and compressive forces exist on the lumens/conduits at the top and bottom of the bend, as depicted by arrows **1709** (extension forces) and **1710** (compressive forces) respectively. These forces exist because the distance along the top of the bend is longer than the neutral axis, and the distance along the inside of the bend is shorter than the neutral axis.

FIG. **17**F illustrates the mechanics of articulating the distal bending section **1707** of the endoscope **1700** in the same direction as bend τ, where one would pull tendon **1703**. This results in compressive forces along the length of the flexible instrument (as previously described), and tendon **1703** also exerts downward forces against the non-linear conduit through which it passes, which applies an additive compression in the shaft **1708** previously compressed by the anatomical tortuosity. Since these compressive leads are additive, the shaft **1708** will further bend in the same direction as the distal bending section **1707**. The additional compressive force along the non-linear conduit may be undesirable because: (i) it may unintentionally force the flexible instrument against the anatomy; (ii) potential for injury distracts the operator because he/she has to constantly monitor what the shaft is doing, when he/she should be able to "assume" the anatomy is governing the profile of the instrument shaft; (iii) it is an inefficient way to bend the instrument, (iv) it is desired to isolate bending at the distal section to aid in predictability and controllability (i.e., ideal instrument will have bending section that bends as commanded and is not a function of the anatomical non-linear path), and (v) it forces a user to pull on a tendon **1103** an unpredictable additional length (ϕ+θ+τ).

FIG. **17**G illustrates a scenario where one desires to articulate the distal end opposite to bend τ, requiring pulling tendon **1702**. Pulling tendon **1702** applies a compressive load **1711** along the top of the curve, which is in contrast to the extension loads for the bend in its resting state as shown in FIG. **17**E. Tendons **1702** will attempt to return to its lowest energy state, i.e., where the compressive load **1711** rests on the inside of the bend τ, and cause the shaft **1708** to rotate in the direction of the arrow **1712** so that the tendon **1702** rests on the inside of the bend τ. As shown in FIG. **17**H, the rotation **1712** from tension on tendon **1702** moves the compressive load **1711** to return to the inside of the bend and causes the distal bending section **1707** to curl back in the direction of bend τ, resulting in articulation opposite to that intended. The tension on tendon **1702**, and the ensuing rotation **1712**, in practice returns endoscope **1700** to the same state as in FIG. **17**F. The phenomenon where the distal end articulation curves back towards bend τ is known as "curve alignment." It will be appreciated that curve alignment results from the same forces that cause muscling, wherein those forces result in undesirable lateral motion in the case of muscling and undesirable rotational motion in the case of curve alignment. It is noted that the discussions of the theory of muscling and curve alignment is provided not by way of limitation, and embodiments of the present invention are not in any way limited by this explanation.

FIGS. **17**I and **17**J illustrate how the muscling and curve alignment phenomena is substantially resolved through the provision of a helixed section in an embodiment of the present invention, such as **1510** in FIG. **15**. As shown in FIG. **17**I, helixing the control lumens around endoscope **1700**, such as in helixed section **1510** from FIG. **15**, radially distributes compressive loads **1714** from a single tendon **1715** around endoscope **1700**. Because a tensioned tendon **1715** symmetrically transmits the compressive load **1714** in multiple directions around the neutral axis, the bending moments imposed on the shaft are also symmetrically distributed around the longitudinal axis of the shaft, which counterbalance and offset opposing compressive and tensile forces. The distribution of the bending moments results in minimal net bending and rotational forces, creating a lowest energy state that is longitudinally parallel to the neutral axis, as represented by the dotted line **1816**. This eliminates or substantially reduces the muscling and curve alignment phenomena.

In some embodiments, the pitch of helixing can be varied to affect friction and the stiffness of the helixed section. For example, the helixed section **1510** may be shorter to allow for a larger non-helixed section **1509**, resulting in a larger articulating section and possibly less friction.

Helical control lumens, however, create several trade-offs. Helical control lumens still do not prevent buckling from tension in the tendons. Additionally, while muscling is greatly reduced, "spiraling"—the curving of the shaft into a spiral, spring-like pattern due to tension in the tendons—is very common. Moreover, helical control lumens requires compensation for additional frictional forces as the tendon travels through the lumen for longer distances.

FIG. **18** illustrates the structure of a flexible endoscopic tool with an axially stiff tube within a lumen, in accordance with an embodiment of the present invention. In FIG. **18**, a section of an endoscopic tool has a single lumen **1801** with a pull wire **1802** wrapped in a helical pattern around the shaft **1800**. Inside the lumen, an axially stiff tube **1803** "floats" around the pull wire **1802** and within the lumen **1801**. Anchored at the beginning and end of the helical portion of the shaft **1800**, the floating tube **1803** extends and compresses in response to tension in pull wire **1802** and external tortuosity, relieving the walls of lumen **1801** from the extension and compression forces. In some embodiments, the tube **1803** may be anchored by control rings at the beginning and end of the lumen. Alternatively, tube **1803** may be anchored using solder, welding, gluing, bonding, or fusing methods to the beginning and end of the lumen. In some embodiments, geometric engagement, such as flared geometries, may be used to anchor tube **1803**. In various embodiments, the tube **1803** may be formed from hypodermic tubes, coil pipes, Bowden cables, torque tubes, stainless steel tubes, or nitinol tubes.

The embodiment in FIG. **18** may be constructed by fixedly attaching the tubes to a distal end piece and proximal end piece and collectively twisting the tubes by rotating either or both end pieces. In this embodiment, the rotation of the end piece(s) ensures that the tubes are helixed in the same pitch, manner, and orientation. After rotation, the end pieces may be fixedly attached to the lumen to prevent further rotation and restrict changes to the pitch of the helixing.

FIG. **19** illustrates the structure of a helical pattern within a lumen of a flexible endoscopic tool, in accordance with an embodiment of the present invention. In FIG. **19**, lumen **1900** contains structures **1901** and **1902** that form a helical or spiraled pattern along its walls. In preferred embodiments, the structures are formed from materials that are axially stiff and tube-like in shape. In some embodiments, the structures may be formed from hypodermic tubes ("hypo tube"), coil pipes, or torque tubes. As shown by structures **1901** and **1902**, the structures may have different starting points along the walls of lumen **1900**. The materials, composition, and characteristics of structures **1901** and **1902** may also be selected and configured for desired stiffness and length. The pitch of the helical pattern formed by structures **1901** and **1902** may also be configured for a desired stiffness and flexibility of lumen **1900**. In some embodiments, lumen **1900** may be the main central lumen of a flexible endoscope, such as leader **1600** from FIG. **16**.

FIG. **20**A illustrates an endoscopic tool from a robotic endolumenal system, in accordance with an embodiment of the present invention. Endoscopic tool **2000** may comprise of a flexible shaft section **2001** proximal to a support base (not shown) and a flexible articulating section **2002** coupled to a distal tip **2003**. Similar to the leader **2005**, endoscopic tool **2000** may be articulated by placing tensile loads on tendons within the shaft.

FIG. **20**B illustrates an alternative view of endoscopic tool **2000** from FIG. **20**A. As shown in FIG. **20**B, the distal tip **2003** may comprise a working channel **2004**, four light emitting diodes **2005**, and a digital camera **2006**. In conjunction with the LEDs **2005**, the digital camera **2006** may be used, for example, to capture real-time video to assist with navigation within anatomical lumens. In some embodiments, the distal tip **2003** may comprise an integrated camera assembly which houses a digital imaging means and illumination means.

The working channel **2004** may be used for the passage of intraoperative instruments, such as bending flexures for precise articulation at an operative site. In other embodiments, working channels may be incorporated to provide additional capabilities such as flush, aspiration, illumination or laser energy. The working channel may also facilitate the routing of control tendon assemblies and other lumens needed for the aforementioned additional capabilities. The working channel of the endoscopic tool may also be configured to deliver a variety of other therapeutic substances. Such substances may be cryogenic for ablation, radiation, or stem cells. These substances may be precisely delivered precisely to a target site using the insertion, articulation, and capability of the endoscopic tool of the present invention. In some embodiments, the working channel may be as small at 1.2 millimeters in diameter.

In some embodiments, an electromagnetic (EM) tracker may be incorporated into the distal tip **2003** in order to assist with localization. As will be discussed later, in a static EM field generator may be used to determine the location of the EM tracker, and thus distal tip **2003** in real-time.

Images from camera **2006** may be ideal for navigating through anatomical spaces. Thus, obscuring of the camera **2006** from internal bodily fluids, such as mucus, may cause problems when navigating. Accordingly, the distal end **2003** of endoscopic tool **2000** may also include means for cleaning the camera **2006**, such as means for irrigation and aspiration of the camera lens. In some embodiments, the working channel may contain a balloon that may be inflated with fluid around the camera lens and aspirated once the lens was clear.

The endoscopic tool **2000** enables the delivery and manipulation of small instruments within the endolumenal space. In a preferred embodiment, the distal tip may be miniaturized in order to perform endolumenal procedures, maintaining an outer diameter of no more than three millimeters (i.e., nine French).

FIG. **21** illustrates the distal end of an endoscopic tool, in accordance with an embodiment of the present invention. As in FIG. **21**A, endoscopic tool **2100** includes a distal end **2101** with an outer casing **2102**. Casing **2102** may be constructed from a number of materials including stainless steel and polyether ether ketone (PEEK). The distal end **2101** may be packed with a working channel **2103** for slidingly providing tool access and control. The distal end **2101** may also provide for an array of light emitting diodes **2104** for illumination with use of the camera **2105**. In some embodiments, the camera may be part of a larger sensor assembly that includes one or more computer processors, a printed circuit board, and memory. In some embodiments, the sensor assembly may also include other electronic sensors such as gyroscopes and accelerometers (usage discussed later).

8. Endoscopic Tool Manufacture.

In background, steerable catheters are traditionally manufactured by braiding wires or fibers, i.e., braid wire, around a process mandrel with pull lumens in a braiding machine, i.e., braider, and a polymer jacket applied over the braid wires. Embodiments of the sheath and leader endoscopic tools may be constructed using aspects of steerable catheter construction methodologies.

FIG. **22** illustrates a flowchart for a method of constructing an endoscopic device with helixed lumens, in accordance with an embodiment of the present invention. To start, in step **2201**, a main process mandrel may be selected to create a cavity in the endoscope for a central lumen that may be used a working channel. Supplemental mandrels may be selected to create cavities in the wall of the endoscope for use as control (pull) lumens. The main process mandrel may exhibit larger outer diameters (OD) than the supplemental mandrels to reflect the relative size differential between a working channel and pull lumens. The supplemental mandrels may be constructed a metal or thermoset polymer that may or may not be coated with a lubricious coating, such as PTFE.

In step **2202**, the main process mandrel may be inserted into a feed tube of a braider that rotates relative to a fixed braid cone support tube and braid cone holder. Similarly, the supplemental mandrels may also be inserted into the feed tube in parallel fashion to the main process mandrel. In traditional endoscope construction, smaller supplemental mandrels are passed through the center of the horn gears for braiding.

In step **2203**, using a puller with a tread, the main process mandrel may be advanced through the feed tube. As the main process mandrel progresses, it eventually emerges through a center hole in a nose cone. Similarly, the supplemental mandrels are advanced through to also emerge through outer holes in the nose cone. This contrasts with traditional endoscope construction, where supplemental mandrels are typically advanced through separate feed tubes to emerge from the center of the horn gears.

In step **2204**, the main process mandrel and supplemental mandrels are braided together using braid wire as they emerge through the nose cone. The nose cone provides a round, smooth shape on which the braid wire from the surrounding horn gears may easily slide around the main process mandrel during the braiding process. As both the main process mandrel and supplemental mandrels emerge from the nose cone, the nose cone rotates, ensuring that the supplemental mandrels in the outer holes are braided in a spiraled fashion around the main process mandrel. As the main process mandrel and supplemental mandrels are being braided together, the horn gears translate and rotate to lay braid wire around both the main process mandrel and supplemental mandrels at a pre-determined pattern and density.

This method of braiding is significantly different from traditional methods of endoscope construction, where the nose cone is typically held in a position that is radially fixed relative to the braid cone holder using a set screw keyed to the braid cone holder. Thus, specialized hardware is required for the braiding process in order to manufacture catheter-like endoscopes with helical control lumens.

FIG. **23** illustrates a specialized system for manufacturing an endoscope with helical pull lumens, in accordance with an embodiment of the present invention. In system **2300**, the nose cone **2301** may be fixedly coupled to a rotating feed tube **2302** using a set screw that holds the nose cone **2301** in a fixed position relative to the feed tube **2302**. Thus, nose cone **2301** rotates as the feed tube **2302** rotates. In contrast, traditional systems typically use a set screw to fixedly couple the nose cone **2301** to the braid cone support holder **2305**, which does not rotate.

The center hole **2303** of the nose cone **2301** may be aligned with the rotating feed tube **2302** in order to smoothly pull the main process mandrel **2304** through both structures. In some embodiments, the rotating feed tube **2302** has an outside diameter less than the interior diameter of the braid cone support tube **2306**, also known as a mandrel guide tube, and an interior diameter larger than the circumferential space of the center hole **2303** of the nose cone **2301**. The rotating feed tube **2302** may generally be large enough for the main process mandrel **2304** and the supplemental mandrels to be passed through to the nose cone **2301** without entanglement. In some embodiments, the rotating feed tube **2302** may be long enough to pass through the center of the horn gears of the braider. In some embodiments, the rotating feed tube **2302** may be attached to a mechanism that may hold bobbins of material for the supplemental mandrels that will be passed through the feed tube **2302** to supplemental holes around the nose cone **2301**.

In some embodiments, the feed tube **2302** may be attached to a drive mechanism that controls the rate of rotation of the feed tube **2302** and thus the rotation of the nose cone **2301**. In some embodiments, the drive mechanism may be a rotating gear **2307**. As the braider is braiding the braid wires **2308** around the main process mandrel **2304**, the drive mechanism is either geared to the braider itself or independently controlled to vary or hold constant the rate of rotation of the rotating feed tube **2302** and thus the rate of rotation of the nose cone **2301**. The rate of rotation and the rate of braiding will govern the pitch of the supplemental mandrels on the main process mandrel **2304**. As discussed earlier, this may affect the flexibility, stiffness, and "pushability" of the device.

FIG. **24** illustrates a specialized nose cone for manufacturing helical lumens in an endoscopic device, in accordance with an embodiment of the present invention. Rotating the nose cone **2400** at the same time that the main process mandrel **2401** is pulled through the nose cone **2400** allows for supplemental mandrels **2402**, **2403**, and **2404** to be applied in a helical pattern around the mandrel **2401** through supplemental holes **2405**, **2406**, and **2407** respectively that surround the center hole **2408**, similar to how the horn gears braid the braid wire around the main process mandrel **2401**.

In another embodiment, varying the circumferential orientation of the pull lumens may change the stiffness of the helical section of the endoscope. In manufacture, this may be achieved by altering the pitch of the supplemental, spiraling mandrels. As the pitch (i.e., the angle off the longitudinal axis) of the mandrels increases, the bending stiffness of the braided composite decreases. Conversely, as the pitch of the supplemental mandrels decreases, the bending stiffness increases. As shown in FIG. **15**B, in some embodiments, the pitch of the supplemental mandrels may be varied within the helixed portion (**1510**). In those embodiments, the bending stiffness of the braided composite may vary even within the helixed portion.

Returning to FIG. **22**, in step **2205**, upon completion of the braided process, a polymer coating or jacket may be sheathed, heated, and bonded to the braiding composite. The polymer coating may also be applied in an over-extrusion or a film-cast process. In step **2206**, after bonding, the mandrels may be removed from the braided composite to create a central lumen or working channel (main process mandrel) for camera and light tools, and several control lumens (supplemental mandrels) for steering control. Having removed the mandrels, the braided composite may be finished for completion (**2207**).

During the braiding process, the braiding machine may be stopped to make alterations to the braided composite. In some embodiments, one alteration may be the addition of straight wires or reinforcement rods. Reinforcement rods may significantly change the buckling, axial and bending stiffness of a braided laminated composite. Reinforcement rods may be particularly helpful for longer endoscopes which may require specialized anti-buckling construction or manual assistance to reduce the buckling of the device so that it may be inserted into a patient. In some embodiments, the braiding machine may be configured to selectively braid reinforcement rods that may be pulled from holes in the nose cone onto the main process mandrel, where the reinforcement rods are captured and held in place by the braid wire. The absence of reinforcement rods in the distal region of the resulting endoscope preserves the device's flexibility in the distal end while increasing the stiffness in the proximal region. This combination of properties makes the resulting endoscope easier for a physician to navigate, insert, and push the device into an endolumenal cavity of a patient.

Applying supplemental mandrels onto a main process mandrel using holes in a rotating nose cone provides a number of manufacturing advantages. By using holes in the nose cone, the mandrels are not pushed from the horn gears. Pushing mandrels from the center of the individual horn gears, which are also responsible for weaving the braid wire, results in the mandrels being interwoven with the braid wire, which locks the resulting braid matrix in place longitudinally. This form of construction, known as "zero degree construction," limits the ability of the manufacturer to adjust the braid matrix for desirable flexibility or hoop strength. In zero degree construction, the supplemental mandrel is necessarily confined in an "over-under manner" by the braid, resulting in all clockwise braided braid wire being woven "over" the supplemental mandrels, while all counter-clockwise braided braid wire is woven "under" the supplemental mandrels. As zero degree construction locks the supplemental mandrels in place radially, it may be undesirable where varying the pitch of the supplemental mandrel along the main process mandrel is required.

Additionally, use of the horn gears as a pass-through for the supplemental mandrels limits the number of supplemental mandrels that may be applied to the main process mandrel. For example, a sixteen carrier braider can apply up to eight mandrels, a twenty-four carrier braider can only have up to twelve mandrels. In contrast, use of holes in the nose cone allows any number of mandrels to be passed through to the main process mandrel.

In some embodiments, the supplemental mandrels may be applied to the main process mandrel without the benefit of a second, outer layer of braid wire. Instead, the supplemental mandrels may be applied without braid wire. In those embodiments, the bonded/fused polymer jacket may hold the mandrels, and thus lumens in place. Alternatively, in some embodiments, the mandrels may be held in place using a casting around the braided composite. Since the outer braid layer is absent from the manufacturing endoscopic tool, the diameter and circumference of the device cross-section is reduced. Alternatively, the supplemental mandrels may be held in place by sleeving a polymer jacket over the main process mandrel. In some embodiments, the casting may be the same material as the exterior material for the endoscopic tool.

In some embodiments, the supplemental mandrels may be braided onto the main process mandrel much like the braid wire. For example, in some embodiments, the supplemental mandrels may be braided using the even numbered horn gears, while held in place by braid wire braided using the odd numbered horn gears. In this way, the supplemental mandrels, and thus the lumens may be woven into the walls of the central lumen. As an added benefit, embodiments manufactured using this means also tend to have lower circumferential area.

Alternatively, in some embodiments, the helixed lumen structures may be manufactured using extruded molds. These molds may generate the helixed lumen structures to create a jacket from PTFE, pebax, polyurethane, and nylon. In some embodiments, the extruded structures may be formed using a mold around a braided mandrel.

In some embodiments, the helical lumen construction may be performed by rotating the main process mandrel as it is being drawn through the braider. By rotating the main process mandrel, instead of the nose cone, the supplemental mandrels may be drawn through either a fixed nose cone or through the center of the horn gears during the braiding process. In this embodiment, the nose cone may be fixedly coupled to the nose cone holder and the main process mandrel is rotated as it drawn through the nose cone.

Construction of sheath **1500** from FIG. **15** and leader **1600** from FIG. **16** are substantially the same. Thus, one of skill in the art would understanding that the same principles apply to both tools.

9. Endolumenal Navigation.

In an embodiment of the present invention, navigation of the endoscopic tool through anatomical lumens may involve use of computer-generated three-dimensional maps based on a collection of two-dimensional images created by low dose computerized tomography (CT) scans. Two-dimensional CT scans, each representing a cutaway view of the patient's internal anatomy, may be collected during pre-operative procedures. These scans may be analyzed to determine cavities and anatomical spaces within the patient, such as branches of a lung or the path of a urethra.

Having been analyzed to determine the relevant anatomical spaces within the patient, the spaces may be expressed as lumens with centerline coordinates, i.e., coordinates representing the center of the lumen, in three-dimensional space. The volume of those cavities may be represented as a specific measurement of diameter distance at each centerline coordinate. By tracking the centerline and the corresponding diameter distance measurements, a computer-generated model of a three-dimensional lumen may be generated. Grid coordinate data may thus be used to express three-dimensional spaces and cavities that represent the patient's anatomy.

FIG. **25** illustrates the relationship between centerline coordinates, diameter measurements and anatomical spaces. In FIG. **25**A, anatomical lumen **2500** may be roughly tracked longitudinally by centerline coordinates **2501**, **2502**, **2503**, **2504**, **2505**, and **2506** where each centerline coordinate roughly approximates the center of the lumen. By connecting those coordinates, as shown by "centerline" **2507**, the lumen may be visualized. The volume of the lumen may be further visualized by measuring the diameter of the lumen at each centerline coordinate. Thus **2508**, **2509**, **2510**, **2511**, **2512**, and **2513** represent the measurements of the lumen **2500** at coordinates **2501**, **2502**, **2503**, **2504**, **2505**, and **2506**.

In FIG. **25**B, lumen **2500** may be visualized in three-dimensional space by first locating the centerline coordinates **2501**, **2502**, **2503**, **2504**, **2505**, and **2506** in three-dimensional space based on centerline **2507**. At each centerline coordinate, the lumen diameter may be visualized as a two-dimensional circular space with diameters **2508**, **2509**, **2510**, **2511**, **2512**, and **2513**. By connecting those two-dimensional circular spaces in three-dimensions, lumen **2500** may be approximated as three-dimensional model **2514**. More accurate approximations may be determined by increasing the resolution of the centerline coordinates and measurements, i.e., increasing the density of centerline coordinates and measurements for a given lumen or subsection. Centerline coordinates may also include markers to indicate point of interest for the physician, including lesions.

Having expressed, and subsequently generated, a three-dimensional model of the anatomical space, a pre-operative software package may also be used to analyze and derive an optimal navigation path based on the generated module. For example, the software package may derive shortest path to a single lesion (marked by a centerline coordinate) or several lesions. This path may be presented to the operator intra-operatively either in two-dimensions or three-dimensions depending on the operator's preference.

FIG. **26** illustrates a computer-generated three-dimensional model representing an anatomical space, in accordance with an embodiment of the invention. As discussed earlier, model **2600** may be generated using centerline **2601** that was obtained by reviewing CT scans that were performed preoperatively. In some embodiments, computer software may be able to map the optimum path **2602** for the endolumenal system to access an operative site **2603** within model **2600**, and thus the corresponding anatomical space. In some embodiments, the operative site **2603** may be linked to an individual centerline coordinate **2604**, which allows a computer algorithm to topologically search the centerlines of model **2600** for the optimum path **2602** for the endolumenal system.

Tracking the distal end of the endoscopic tool within the patient's anatomy, and mapping that location to placement within a computer model, enhances the navigational capabilities of the endolumenal system. In order to track the distal working end of the endoscopic tool, i.e., "localization" of the working end, a number of approaches may be employed, either individually or in combination.

In a sensor-based approach to localization, a sensor, such as an electromagnetic (EM) tracker, may be coupled to the distal working end of the endoscopic tool to provide a real-time indication the progression of the endoscopic tool. In EM-based tracking, an EM tracker, embedded in the endoscopic tool, measures the variation in the electromagnetic field created by one or more static EM transmitters. The transmitters (or field generators), may be placed close to the patient to creates a low intensity magnetic field. This induces small-currents in sensor coils in the EM tracker, which are correlated to the distance and angle between the sensor and the generator. The electrical signal may then be digitized by an interface unit (on-chip or PCB) and sent via cables/wiring back to the system cart and then to the command module. The data may then be processed to interpret the current data and calculate the precise location and orientation of the sensor relative to the transmitters. Multiple sensors may be used at different locations in the endoscopic device, for instance in leader and sheath in order to calculate the individual positions of those components. Thus, based on readings from an artificially-generated EM field, the EM tracker may detect changes in field strength as it moves through the patient's anatomy.

FIG. **27** illustrates a robotic endolumenal system that makes use of an electromagnetic tracker in combination with an electromagnetic field generator, in accordance with an embodiment in the present invention. As robotic system **2700** drives a robotically driven endoscopic tool **2701** into the patient **2702**, an electromagnetic (EM) tracker **2703** at the distal end of the endoscopic tool **2701** may detect an EM field generated by EM field generator **2704**. The EM readings of the EM tracker **2703** may be transmitted down the shaft of the endoscopic tool **2701** to the system cart **2705** and to command module **2706** (which contains relevant software modules, a central processing unit, a data bus and memory) for interpretation and analysis. Using the readings from EM tracker **2703**, display modules **2707** may display the EM tracker's relative position within a pre-generated three-dimensional model for review by the operator **2708**. The embodiments also provide for the use of other types of sensors, such as fiber optic shape sensors. While a variety of sensors may be used for tracking, the choice of sensor may be inherently limited based on (i) the size of the sensor within the endoscopic tool and (ii) the cost of manufacturing and integration the sensor into the endoscopic tool.

Prior to tracking a sensor through the patient's anatomy, the tracking system may require a process known as "registration," where the system finds the geometric transformation that aligns a single object between different coordinate systems. For instance, a specific anatomical site on a patient has two different representations in the CT model coordinates and in the EM sensor coordinates. To be able to establish consistency and common language between these coordinate systems, the system needs to find the transformation that links these two representations, i.e., registration. In other words, the position of the EM tracker relative to the position of the EM field generator may be mapped to a three-dimensional coordinate system to isolate a location in a corresponding three-dimensional model.

In some embodiments, registration may be performed in several steps. FIG. **28** illustrates a flow diagram for a registration process, in accordance with an embodiment of the present invention. To start, in step **2801**, the operator must first position the working end of the endoscopic tool at a known starting location. This may involve using video imagery data from the endoscopic camera to confirm the starting location. Initial positioning may be accomplished by identifying anatomical features through a camera located at the working end of the endoscope. For example, in bronchoscopy, registration may be performed by locating the base of the trachea, distinguished by locating the two main bronchial tubes for the left and right lung. This location may be ascertained using video images received by the camera in the distal end of the endoscopic. In some embodiments, the video data may be compared to different cross sectional views of a pre-generated computer model of the patient's anatomy. By sorting through cross-sectional views, the system may identify the location associated with the cross-section with the smallest amount of differences, or "errors," to find the "match."

In step **2802**, the operator may "drive" or "extend" the endoscopic tool into unique anatomical spaces that have already been mapped. For example, in bronchoscopy, the operator may drive the endoscope down unique bronchial paths from the base of the trachea. Because the base of the trachea splits into two bronchial tubes, an operator may drive the endoscopic tool into one tube and track the working end of the endoscopic tool using an EM tracker.

In step **2803**, the operator monitors the relative travel of the endoscopic tool. Monitoring of the endoscopic tool may make use of either the EM tracker or fluoroscopy to determine relative movement of the endoscopic tool. Evaluation of the relative displacement of the working end of the endoscopic tool may be compared the computer model generated from pre-operative CT scan data. In some embodiments, the relative movement may be matched with centerlines in the computer model, where the transformation matrix leads to the least error is the correct registration. In some embodiments, the system and operator may track insertion data (discussed below) and orientation data from an accelerometer and/or gyroscope (discussed below).

In step **2804**, the operator may decide to drive into more anatomical spaces (**2802**) and collect more locational information (**2803**) prior to comparing and analyzing the positional data. For example, in bronchoscopy, the operator retract the endoscope from one bronchial tube back the tracheal tube and drive the endoscope into another bronchial tube in order to collect more positional data. Once the operator is satisfied, the operator may stop driving (**2802**) and monitoring positional data (**2803**) and proceed to process the data.

In step **2805**, the system may analyze the collected positional data and compare the data to pre-generated computer models to register the displacement of the endoscope within patient's anatomy to the model. Therefore, by comparing the movement in the patient's anatomy to the three-dimensional model of the patient's anatomy, the system may be able to register the tracker relative to both spaces—three-dimensional computer model vs. patient anatomical space. After analysis, the registration process may be complete (**2806**).

In some cases, it may be necessary to perform a "roll registration" in order to confirm the orientation of the endoscopic tool. This may be particularly important in step **2801** prior to driving into un-registered anatomical spaces. In bronchoscopy, proper vertical orientation ensures that the operator may distinguish between the right and left bronchi. For example within the base of the trachea, images of the left and right bronchi may appear very similar regardless of whether the camera is oriented at zero degrees or one-hundred eighty degrees. Roll registration may also be important because the kinematics of the endoscopic tool typically results in a slight rotation during tortuous navigation within a patient.

Roll registration may be important at the operative site when the working channel may be occupied by the sensor. For example, in embodiments with only a single working channel, upon reaching the operative site, the physician may need to remove the EM tracker from the endoscopic tool in order to make use of another tool, such as a grasper or forceps. Upon removal, however, the system may lose its localization capabilities without the EM tracker. Thus, when ready to leave the operative region, insertion of the EM tracker may require that the roll registration be again performed to ensure proper orientation.

In some embodiments, the rotation of the endoscopic tool may be tracked using an accelerometer mounted within the distal working end of the device. Use of an accelerometer to detect gravitational forces on the endoscope provides information regarding the location of the endoscopic tool relative to the ground. The location of the ground relative to the endoscope may be used to solve certain ambiguities. In bronchoscopy, for example, knowing the orientation (0 or 180 degrees) of the distal camera of the endoscope would help determine the appropriate bronchial branch at the start. During navigation, data from the accelerometer to track the direction of gravity, and thus orientation, may also be used to auto-correct the camera image displayed on the control console, ensuring that the displayed image is always oriented vertically.

In a preferred embodiment, a 3-axis MEMS-based sensor chip with an accelerometer may be coupled near the tip of the endoscopic device, on the same printed circuit board as the digital camera. The accelerometer measures the linear acceleration along the three different axes to calculate the velocity and direction of the catheter tip. It accelerometer also measures the direction of gravity and thus provides absolute information about the orientation of the endoscopic device. The accelerometer readings re be transmitted using digital or analog signals through a communication protocol like I2C. The signal may be transmitted through wiring to the proximal end of the catheter and from there to the system cart and command module for processing.

In a three-axis sensor, the accelerometer may be able to determine location of the ground relative to the endoscope. If the endoscope does not roll or bend up to ninety degrees, a two axis accelerometer could be also be useful. Alternatively, a one-axis sensor may be useful if the axis of the accelerometer remains perpendicular to the direction of gravity, i.e., perpendicular to the ground. Alternatively, a gyroscope may be used to measure the rate of rotation, which may then be used to calculate the articulation of the endoscopic device.

Some embodiments make use of an EM tracker in combination with the accelerometer to supplement any orientation readings from the accelerometer. In some embodiments, use of fluoroscopy to track the endoscopic tool may also supplement the registration process. As known in the art, fluoroscopy is an imaging technique that uses X-rays to obtain real-time moving images of the internal structures of a patient through the use of a fluoroscope. Two-dimensional scans generated by fluoroscopy may assist with localization in certain situations, e.g., identifying the relevant bronchi.

Tracking using fluoroscopy may be performed using a plurality of radio-opaque markers on the endoscope. Many features of the endoscope are naturally radio-opaque to x-rays, including the camera head, the control ring and pull wires; thus, the marker location together with the metallic components of the endoscope may be used to obtain a three-dimensional transformation matrix. Once registration has happened, visual images detecting branch locations may be precisely correlated to the three-dimensional model. In addition, the full branch length and branch location in 3D can be measured and enhanced in the map.

In contrast to a sensor-based approach, vision-based tracking involves using images generated by a distally-mounted camera to determine the location of the endoscopic tool. For example, in bronchoscopy, feature tracking algorithms may be used to identify circular geometries corresponding to bronchial paths and track the change of those geometries from image to image. By tracking the direction of those features as they move from image to image, the system may be able to determine which branch was selected, as well as the relative rotational and translational motion of the camera. Use of a topological map of the bronchial paths may further enhance vision-based algorithms.

In addition to feature based tracking, image processing techniques such as optical flow may also be used to identify branches in the airway topology in bronchoscopy. Optical flow is the displacement of image pixels from one image to the next in a video sequence. With respect to bronchoscopy, optical flow may be used to estimate the movement of the tip of the scope based on changes in the camera images received at the tip of the scope. Specifically, in a series of video frames, each frame may be analyzed to detect translation of the pixels from one frame to the next. For example, if the pixels in a given frame appear to translate to the left in the next frame, the algorithm would infer that the camera, and in turn the tip of the scope, moved to the right. Through comparing many frames over many iterations, movement (and thus location) of the scope may be determined.

Where stereoscopic image capture—as opposed to monocular image capture—is available, optical flow techniques may also be used to complement the pre-existing three-dimensional model of the anatomic region. Using stereoscopic image capture, the depth of the pixels in the two-dimensional captured images may be determined to build a three-dimensional map of objects in the camera view. Extrapolating to travel within an anatomical lumen, this technique enables the system to develop three-dimensional maps of the local surroundings around the endoscope while navigating in inside the patient's anatomy. These maps may be used to extend the pre-determined three-dimensional computer models where the models either are missing data or of low quality. In addition to a stereoscopic camera apparatus, depth sensors or specific lighting configurations and image capture techniques—such as RGB-D sensors or structure lighting—may need to be used.

Regardless of tracking method—either sensor-based or vision-based—tracking may be improved by using data from the endoscopic tool itself. For example, in endoscopic tool **200** from FIG. **2**, the relative insertion length of sheath **201** and leader **205** may be measured from a known, starting position within the trachea (in the case of bronchoscopy). Using relative insertion length and the centerlines of a three-dimensional model of the patient's bronchial tree, the system may giving a rough estimation of the location of the working end after determining whether the endoscopic tool is located in a branch and the distance traveled down that branch. Other control information from the endoscopic tool may also be used, such as endoscope device articulation, roll, or pitch and yaw.

Real-time imaging based on different imaging modalities would further enhance navigation, particularly at the operative site. Even though tracking may assist with rough navigation to the operative site, additional modalities may be useful when more precise handling is necessary, such when attempting to biopsy a lesion. Imaging tools such as fluorescence imaging, near infrared imaging, oxygen sensors, molecular biomarker images, and contrast dye imaging may help pinpoint the exact coordinates of the lesion in the computer model, and thus assist with operating a biopsy needle at the operative site. In the absence of a precise location, the endoscopic tool may be used to biopsy the entire region of the operative site at a known depth, thus ensuring tissue from the lesion is sampled.

In some cases, the segmented CT scans, and thus the resulting computer models, do not show branches at the periphery of the lung (in the context of bronchoscopy). This may be due to insufficient inflation of the airways during a scan, or because the size of the branches is below the resolution of a CT scan (typically on the order of 1 millimeter). In practice, the robotic system may enhance the computer model during the procedure by noting the location and the position and orientation of the unmapped branch. In some embodiments, the topology structure may allow physicians to mark their location and return to that same location in order to examine the periphery branches. In some embodiments, the endoscopic camera may measure the diameter and shape of the branches based on the capture images, allowing those branches to be mapped based on position and orientation.

10. Endolumenal Procedures.

FIG. **29**A illustrates the distal end of an endoscopic tool within an anatomical lumen, in accordance with an embodiment of the present invention. In FIG. **29**A, endoscopic tool **2900**, comprising a shaft **2901** is shown navigating through an anatomical lumen **2902** towards an operative site **2903**. During navigation, the shaft **2901** may be unarticulated.

FIG. **29**B illustrates the endoscopic tool from FIG. **29**A in use at an operative site within an anatomical lumen. Having reached the operative site **2903**, a distal leader section **2904**, longitudinally aligned with the shaft **2901**, may be extended from shaft **2901** in the direction marked by arrow **2905**. Distal leader section **2904** may also be articulated in order to direct tools towards operative site **2903**.

FIG. **29**C illustrates the endoscopic tool from FIG. **29**B in use at an operative site within an anatomical lumen. In cases where the operative site contains a lesion for biopsy, the distal leader section **2904** may articulate in the direction marked by arrow **2906** to convey an aspiration needle **2907** to target a lesion at operative site **2903**. In some embodiments, distal leader section **2904** may be articulated to direct biopsy forceps to remove samples of anatomical tissues for purposes of intraoperative evaluation. For purposes of activation of that end effector, endoscopic tool **2900** may comprise a tendon operatively coupled to the biopsy forceps.

FIG. **30**A illustrates an endoscopic tool coupled to a distal flexure section within an anatomical lumen, in accordance with an embodiment of the present invention. In FIG. **30**A, an endoscopic tool **3000**, comprising a shaft **3001**, flexure section **3002**, and forceps **3003**, is shown navigating through an anatomical lumen **3004** towards an operative site. During navigation, both the shaft **3001** and distal flexure section **3002** may be unarticulated as shown in FIG. **30**A. In some embodiments, the flexure section **3002** may be retracted within shaft **3001**. The construction, composition, capabilities, and use of flexure section **3002** is disclosed in U.S. patent application Ser. No. 14/201,610, filed Mar. 7, 2014, and U.S. patent application Ser. No. 14/479,095, filed Sep. 5, 2014, the entire contents of which are incorporated by reference.

In some embodiments, the flexure **3002** may be longitudinally-aligned with the shaft **3001**. In some embodiments, the flexure **3002** may be deployed through a working channel that is off-axis (neutral axis) of shaft **3001**, allowing for the flexure **3002** to operate without obscuring a camera located at the distal end of shaft **3001**. This arrangement allows an operator to use a camera to articulate flexure **3002** while shaft **3001** remains stationary.

Similar to other embodiments, different tools, such as forceps **3003**, may be deployed through the working channel in flexure section **3002** for use at the distal end of the flexure section **3002**. In other scenarios, surgical tools such as graspers, scalpels, needles, and probes may be located at the distal end of the flexure section **3002**. In endoscopic tool **3000**, as in other embodiments, the tool at the distal end of the bending section may be substituted intra-operatively in order to perform multiple treatments in a single procedure.

FIG. **30**B illustrates an endoscopic tool from FIG. **30**A with a forceps tool in use at an operative site within an anatomical lumen, in accordance with an embodiment of the present invention. Navigation of endoscopic tool **3000** through anatomical lumen **3004** may be guided by any number of the various navigational technologies discussed above. Once the endoscopic tool **3000** has reached its desired location at the operative site **3006**, flexure section **3002** may articulate in the direction of arrow **3005** in order to orient forceps **3003** towards operative site **3006**. Using forceps **3003**, endoscopic tool **3000** may take a biopsy of the tissue at the operative site **3006**.

FIG. **30**C illustrates an endoscopic tool from FIG. **30**A with a laser device in use at an operative site within an anatomical lumen, in accordance with an embodiment of the present invention. Having reached the operative site **3006**, the flexure section **3002** of endoscopic tool **3000** may be articulated and a laser tool **3007** may be deployed through the working channel of the shaft **3001** and flexure section **3002**. Once deployed, the laser tool **3007** may be directed to operative site **3006** to emit laser radiation **3008** for purposes of tissue ablation, drilling, cutting, piercing, debriding, cutting or accessing non-superficial tissue.

11. Command Console.

As discussed with respect to system **100** from FIG. **1**, an embodiment of the command console allows an operator, i.e., physician, to remotely control the robotic endolumenal system from an ergonomic position. In the preferred embodiment, the command console utilizes a user interface that both (i) enables the operator to control the robotic endoscopic tool, and (ii) displays the navigational environment from an ergonomic position.

FIG. **31** illustrates a command console for a robotic endolumenal system, in accordance with an embodiment of the present invention. As shown in FIG. **31**, command console **3100** may comprise a base **3101**, display modules, such as monitors **3102**, and control modules, such as keyboard **3103** and joystick **3104**. In some embodiments, the command module functionality may be integrated into the system cart with the mechanical arms, such as system cart **101** from system **100** in FIG. **1**.

The base **3101** may comprise of a central processing unit, a memory unit, a data bus, and associated data communication ports that are responsible for interpreting and processing signals, such as camera imagery and tracking sensor data, from the endoscopic tool. In other embodiments, the burden of interpretation and processing signals may be distributed between the associated system cart and the command console **3100**. The base **3101** may also be responsible for interpreting and processing commands and instructions from the operator **3105** through the control modules, such as **3103** and **3104**.

The control modules are responsible for capturing the commands of the operator **3105**. In addition to the keyboard **3103** and joystick **3104** in FIG. **31**, the control modules may comprise other control mechanisms known in the art, including but not limited to computer mice, trackpads, trackballs, control pads, and video game controllers. In some embodiments, hand gestures and finger gestures may also be captured to deliver control signals to the system.

In some embodiments, there may be a variety of control means. For example, control over the endoscopic tool may be performed in either a "Velocity mode" or "Position control mode". "Velocity mode" consists of directly controlling pitch and yaw behaviors of the distal end of the endoscopic tool based on direct manual control, such as through joystick **3104**. For example, right and left motions on joystick **3104** may be mapped to yaw and pitch movement in the distal end of the endoscopic tool. Haptic feedback in the joystick may also be used to enhance control in "velocity mode". For example, vibration may be sent back to the joystick **3104** to communicate that the endoscopic tool cannot further articulate or roll in a certain direction. Alternatively, pop-up messages and/or audio feedback (e.g., beeping) may also be used to communicate that the endoscopic tool has reached maximum articulation or roll.

"Position control mode" consists of identifying a location in a three-dimensional map of the patient and relying on the robotic system to robotically steer the endoscopic tool the identified location based on pre-determined computer models. Due to its reliance on a three-dimensional mapping of the patient, position control mode requires accurate mapping of the patient's anatomy.

Without using the command module **3101**, the system may also be directly manipulated by manual operators. For example, during system setup, physicians and assistants may move the mechanical arms and endoscopic tools to arrange the equipment around the patient and the operating room. During direct manipulation, the system may rely on force feedback and inertia control from human operators to determine the appropriate equipment orientation.

The display modules **3102** may comprise monitors, virtual reality viewing devices, such as goggles or glasses, or other means of display visual information regarding the system and from the camera in the endoscopic tool (if any). In some embodiments, the control modules and display modules may be combined, such as in a touchscreen in a tablet or computer device. In a combined module, the operator **3105** may be able to view visual data as well as input commands to the robotic system.

In another embodiment, display modules may display three-dimensional images using a stereoscopic device, such as a visor or goggle arrangement. Using three-dimensions images, the operator may view an "endo view" of the computer model, a virtual environment of the interior of the three-dimensional computer-generated model of the patient's anatomy to approximate the expected location of the device within the patient. By comparing the "endo view" to the actual camera images, the physician may be able to mentally orient himself and confirm that the endoscopic tool is in the right location within the patient. This may give the operator a better sense of the anatomical structures around the distal end of the endoscopic tool.

In a preferred embodiment, the display modules **3102** may simultaneously display the pre-generated three-dimensional models, the pre-determined optimal navigation paths through the models, and CT scans of the anatomy at the current location of the distal end of the endoscopic tool. In some embodiments, a model of the endoscopic tool may be displayed with the three-dimensional model of the patient's anatomy, to further clarify the status of the procedure. For example, a lesion may have been identified in a CT scan where a biopsy may be necessary.

During operation, camera means and illumination means at the distal end of the endoscopic tool may generate a reference image in the display modules for the operator. Thus, directions in the joystick **3104** causing articulation and rolling of the distal end of the endoscopic tool results in an image of the anatomical features directly in front of the distal end. Pointing the joystick **3104** up may raise the pitch of the distal end of the endoscopic tool with the camera, while pointing the joystick **3104** down may decrease the pitch.

The display modules **3102** may automatically display different views of the endoscopic tool depending on the operators' settings and the particular procedure. For example, if desired, an overhead fluoroscopic view of the endolumenal device may be displayed during the final navigation step as it approached the operative region.

Elements or components shown with any embodiment herein are exemplary for the specific embodiment and may be used on or in combination with other embodiments disclosed herein. While the invention is susceptible to various modifications and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. The invention is not limited, however, to the particular forms or methods disclosed, but to the contrary, covers all modifications, equivalents and alternatives thereof.

What is claimed is:

1. A medical device comprising:

a drive unit; and

a strain gauge longitudinally-parallel with the drive unit, wherein the strain gauge is coupled to the drive unit,

wherein the drive unit is configured to apply a force to a pull wire, and the strain gauge is oriented in a first direction transverse to a path of the pull wire, and

wherein the strain gauge is configured to measure displacement of at least a portion of the drive unit along a second direction corresponding to the path of the pull wire, the measured displacement of the drive unit being in response to the force applied to the pull wire.

2. The medical device of claim **1**, wherein the drive unit comprises a motor, a gear head, and a rotary encoder.

3. The medical device of claim 2, wherein the motor is a brushless motor.

4. The medical device of claim 2, wherein the motor is a direct current servo motor.

5. The medical device of claim 1, wherein the strain gauge is an electrically based strain gauge.

6. The medical device of claim 1, further comprising an electrical circuit board that is configured to amplify a signal generated by the strain gauge.

7. The medical device of claim 6, wherein the circuit board is coupled to the drive unit.

8. The medical device of claim 1, further comprising:
an elongated instrument that comprises:
a shaft with a distal portion and a proximal portion;
an instrument base, coupled to the proximal portion of the shaft, that contains a chamber that contains a spool that is configured to rotate within the chamber,
wherein the spool is not fixedly coupled to the chamber and the drive unit is configured to torque the spool.

9. The medical device of claim 8, wherein the chamber is configured to be concentrically aligned with the longitudinal axis of the drive unit.

10. The medical device of claim 8, wherein the predetermined path of the pull wire is within the shaft.

11. The medical device of claim 8, wherein the spool is configured to convey force from the drive unit to the pull wire.

12. The medical device of claim 11, wherein a portion of the pull wire is wrapped around the spool.

13. The medical device of claim 8, wherein the elongated instrument is detachable from the drive unit.

14. The medical device of claim 8, wherein the spool is configured to be positively coupled to the drive unit.

15. The medical device of claim 8, wherein the instrument base is configured to be positively coupled to the drive unit.

16. The medical device of claim 8, wherein the elongated instrument is configured to perform endoscopic surgical procedures.

17. The medical device of claim 8, wherein the elongated instrument further comprises an imaging means coupled to the distal portion of the shaft.

18. The medical device of claim 1, further comprising a device interface configured to connect with an arm interface on a mechanical arm.

19. The medical device of claim 18, wherein the device interface is configured to receive a control signal from the mechanical arm and transmit a sensor signal to the mechanical arm through the arm interface.

20. The medical device of claim 19, wherein the control signal is configured to control the drive unit.

21. The medical device of claim 1, wherein:
the drive unit comprises a first end and a second end opposing each other in the first direction,
the strain gauge comprises a first end and a second end opposing each other in the first direction,
the medical device further comprises:
a motor mount coupling the first end of the drive unit to the first end of the strain gauge, and
a strain gauge mount coupling the second end of the drive unit to the second end of the strain gauge.

22. The medical device of claim 21, wherein the strain gauge is further configured to measure displacement of the motor mount with respect to the strain gauge mount in the second direction.

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